UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

VENTANA MEDICAL SYSTEMS, INC., Plaintiff, v. VISION BIOSYSTEMS INC., Defendant.	)	C.A. No. 05-CV-10614-GAO

DECLARATION OF ROSS BARROW IN SUPPORT OF VISION'S MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT

I, Ross Barrow, hereby declare as follows:

1. I am the Chief Operating Officer of Vision BioSystems Pty Ltd (formerly known as Vision BioSystems Ltd), parent corporation to Vision BioSystems, Inc. ("Vision"). If called as a witness to testify, I could and would competently testify to the matters asserted herein.

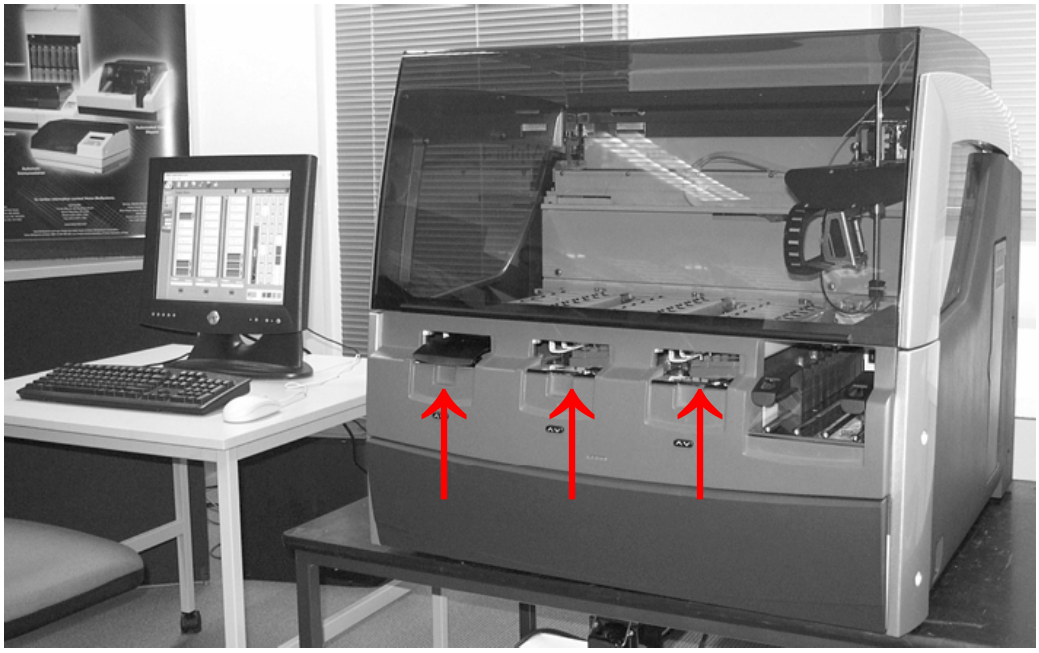
2. The Vision Bond-X and Bond-maX instruments ("Bond instruments") are automated instruments used in staining human tissue samples on slides for diagnostic analysis.

3. The current version of the Bond instruments, and the one that is accused of infringement in this litigation, prints slide labels with slide identifiers that are alphanumeric, i.e., a series of letters and/or numbers. These labels are placed on the slides, and the labeled slides are loaded into the instrument's processing module. When a staining run is started, an imager captures an image of each slide label and sends it to a host computer. The alphanumeric characters on the slide label are then recognized by the computer using Optical Character Recognition ("OCR").

The "Bond-OCR" instrument does not print bar codes on slide labels, and the "Bond-OCR" instrument does not read slide bar codes.

4. The Bond instrument and a slide for the Bond instrument are shown below. The large structure is the Bond processing module in which the staining procedures are performed. The processing module is connected to a host computer, as shown.

Bond Instrument



Slide

5. The processing module has three slide bays, indicated with red arrows above, in which to load trays of slides. One slide, with the slide label, is shown to the right. As mentioned above, the slide labels for the "Bond-OCR" use a string of letters and numbers, e.g., "OOFL OU6." Once the slides are loaded into the processing module and the operator starts the run, an imager in the processing module takes a picture of each slide label and sends the picture to the computer. The computer then reads the image using OCR technology.

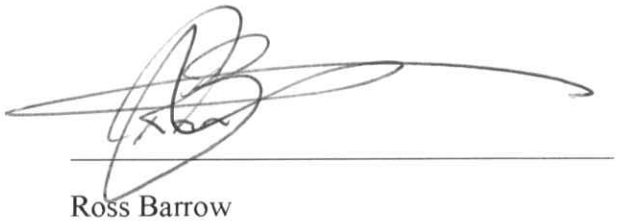
6. The "Bond-OCR" provides an advantage that cannot be realized using bar codes. If the computer is unable to automatically identify a slide—such as if the label is skewed—the slide

can still be identified by the operator of the machine. When the "Bond-OCR" system is unable to automatically identify a slide, the system software displays an image of the label on the host computer screen. The operator can then read the displayed image and manually identify the slide to the computer. If the label carried only a bar code, the operator would not be able to read the label, since bar codes, unlike OCR letters and numbers, are not readily readable by humans. Thus, unlike a bar code instrument, the "Bond-OCR" provides operators with the ability to continue a run even if the instrument cannot automatically recognize a slide label.

7. Attached as Exhibit A hereto is the current User Manual for the "Bond-OCR" instrument. Section 7.5 on page 129 describes the slide identification. The section entitled "assisted slide identification" on pages 109-110 describes the ability of an operator to manually identify a slide if the computer is unable to automatically recognize a slide.

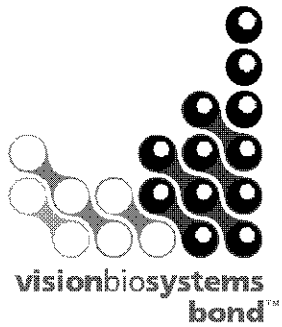
I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Executed this 14th day of June, 2007.



Ross Barrow

EXHIBIT A



bond™ system

user manual

Doc. 21.7532.500 Rev F01

intended use statement

The Bond system is designed for immunostaining histological and cytological specimens mounted on microscope slides.

trademarks

Vision BioSystems and logo design and Bond logo design are trademarks of Vision Systems Limited and are used under license. Other trademarks are the property of their owners.

Vision BioSystems Limited is ISO9001 certified.

Vision BioSystems Limited, ABN 72 008 582 401, is a wholly owned subsidiary of Vision Systems Limited.
*Authorized Representative: Vision BioSystems is a division of Vision Systems (Europe) Ltd.

important information for all users

The components of the Bond system are supplied only for the purposes of the intended use specified.
You must not connect or install equipment or software that is not approved by Vision BioSystems, or configure equipment or software in a manner that is not approved by Vision BioSystems.

The Processing Module has been designed to safeguard the operator and specimens, provided it is operated according to the instructions in the accompanying documentation.

Installation and repairs must only be carried out by qualified service personnel authorized by Vision BioSystems.

It is the responsibility of the owners and operators of the Bond system to protect the system from external causes of damage, including damage by viruses or other software that is not installed or approved by Vision BioSystems, even if that other software is performing within expectation. Special care should be exercised where the Bond system is connected to networked devices, including those connected to the Internet.

Warranty claims can be made only if the system has been used for the intended use and operated according to the user documentation provided. Vision BioSystems cannot assume liability for any damage or loss resulting from inappropriate handling, failure to protect the system, and/or misuse of the product, and any of these conditions will invalidate the warranty or service contract.

Due to a policy of continuous improvement, Vision BioSystems reserves the right to change specifications without notice.

software licence terms

1 defined terms & interpretation

1.1 defined terms

In this agreement:

"Confidential Information" means all information:

(a) treated by Vision as confidential or of its nature confidential; and

(b) disclosed by Vision to the Licensee or of which the other party becomes aware,

except information:

(c) the other party creates independently of Vision; or

(d) that is public knowledge (otherwise than as a result of a breach of confidentiality by the Licensee or any of its permitted disclosees).

"Designated Computer" means the computer or microprocessor controlled unit supplied by Vision to the Licensee under the Supply Agreement or otherwise recommended for use by Vision.

"Documentation" means the manuals, user documentation, proprietary notices, product catalog, website notices and bulletins generally supplied by Vision with or relating to the Software.

"Effective Date" means the date the Goods, as defined in the Supply Agreement, are delivered by Vision.

"Intellectual Property" means all existing and future intellectual property rights including:

(a) patents, copyright (including all copyright and software), software and associated documentation including the specific design and structure of individual programs, registered designs, trade marks, proprietary documentation and notices, and any right to have information or know-how kept confidential; and

(b) any application or right to apply for registration of any of the rights referred to in **a** above.

"Licensee" means the Purchaser or lessee of the Goods containing the Software, or, where the Licensee is a distributor of the Goods containing the Software, the end user of the Goods containing the Software.

"Licensor IP" means all Intellectual Property relating to:

(a) the Software and Documentation;

(b) any modifications, upgrades, new versions or new releases of the materials referred to in **a** above; and

(c) other works created by Vision in the course of, or as a result of, performing this Agreement.

"Release" means each release of a new Version of the Software.

"Software" means any program, firmware or electronic files that provides instructions or data to a computer or microprocessor and, shall for the purposes of this agreement, include original versions, modified versions, upgrades, updates, bug fixes, and backup copies.

"Supply Agreement" means the agreement between the Licensee and Vision, or where the Licensee is not a direct customer of Vision, between Vision's distributor and Vision, for the sale, lease or use of the Goods.

"Third Party Material" means any Material owned by a third party that is not a Related Body Corporate (as that term is defined in the *Corporations Act 2001* (Cth)) of Vision.

1.2 other definitions

In this agreement, "Goods", "Purchaser", and "Vision" have the same meaning as in the Supply Agreement.

2 grant of licence

2.1 licensee gives consent

The Licensee agrees to be bound by all the terms of this Licence by downloading or installing the Software, or by agreeing to purchase, lease or otherwise use the Software or the Goods containing the Software.

2.2 vision grants licence

Subject to this agreement, Vision grants the Licensee a non-transferable, non-exclusive licence to use the Software and Documentation for its internal business purposes in accordance with the terms of this agreement.

3 restrictions on use

The Licensee must:

(a) only use the Software on the Designated Computer and in conformity with:

(i) laboratory practices that are consistent with industry practice;

(ii) all applicable laws, regulations, guidelines and decisions of judicial or regulatory bodies;

(iii) any patent or other proprietary rights of third parties; and

(iv) as envisaged by the Documentation, and this agreement;

(b) not install, or procure the installation of, any software on the Designated Computer without Vision's prior written consent;

(c) not copy all or part of the Software or Documentation, or allow all or part of the Software or Documentation to be copied (other than one copy of the Software for backup purposes), without obtaining Vision's prior written permission;

(d) not publish, distribute or commercialise all or part of the Software or Documentation, or any adaptation, modification or derivative of the Software or Documentation;

(e) not sell, rent, lease, sub-license, assign or transfer all or part of the Software or Documentation or any of its rights under this agreement;

(f) not use the Software or the Documentation for the benefit of any third party, or disclose the Software or the Documentation to any third party, except with Vision's prior written consent;

(g) not adapt, reverse engineer, make error corrections, or otherwise modify the Software or Documentation or create derivative works based on the Software or Documentation (other than to the extent permitted by applicable copyright laws) or permit third parties to do the same;

(h) not decompile, decrypt, reverse engineer, disassemble or otherwise reduce the Software to human readable form to gain access to trade secrets or confidential information in the Software or permit third parties to do the same; and

(i) comply with any reasonable directions of Vision from time to time in relation to the installation or use of the Software and the Documentation.

4 intellectual property

4.1 licensor IP

All Licensor IP, including but not limited to any images, audio, video and text in the Software, is owned by or licensed to Vision, and no Licensor IP is transferred to the Licensee under this agreement.

4.2 proprietary markings

The Licensee must not alter or remove any notices of proprietary rights, any rights management information or any serial numbers appearing on, attached to or incorporated in Licensor IP or any copies thereof, and must not use or attempt to register any trademark, trade name, business name or company name which is confusingly similar to any trademark or trade name of Vision.

4.3 violations of intellectual property

The Licensee must:

(a) notify Vision immediately if it knows of or suspects any unauthorised use, or violation, of any Licensor IP; and

(b) provide promptly, at its cost, all assistance reasonably requested by Vision to protect the relevant rights in Licensor IP and prosecute any claims arising from such uses or violations.

4.4 compliance

The Licensee must comply, at all times, with any terms and conditions relating to the Third Party Material notified to the Licensee by Vision and/or the third party supplier of that Third Party Material.

5 upgrades and support

5.1 new releases and new versions

Vision may, at its sole discretion, provide the Licensee with new Releases or new Versions of the Software.

5.2 installation

If requested by the Licensee to do so, Vision, its designated distributor or agent may, at its sole discretion, install a new Release or new Version of the Software on the Designated Computer.

5.3 downloading of data

Vision, or its designated agent may, at its sole discretion, download data that has been generated by the use of the Software by the Licensee as a means of debugging Software faults and otherwise analyzing the performance of the Software or Goods containing the Software supplied by Vision under the Supply Agreement.

6 back up and security of data

It is the Licensee's responsibility to:

(a) perform regular backups of data and to store these; and

(b) provide contingency plans for the event of a failure of any sort (eg: fire, flood, and theft);

and Vision has no liability (including for negligence) for any loss whether direct or indirect, that could have been prevented by the Licensee performing the above responsibilities, or which occurs as a consequence of inadequate back up, computer viruses or the ongoing functions of computer hardware (including backup hardware), whether supplied by Vision or any other supplier.

7 confidentiality and privacy

7.1 use and disclosure

The Licensee must, in relation to the Confidential Information:

(a) keep it confidential;

(b) use it only as permitted under this agreement and only disclose it:

(i) to employees, contractors and agents that have a need to know and who have undertaken to comply with this clause 7; or

(ii) to the extent (if any) the Licensee is required by law to do so; and

(c) promptly comply with any request by Vision to return or destroy the Confidential Information unless required by law to be retained.

7.2 recipient's obligations

The Licensee must:

(a) safeguard the Confidential Information from unauthorised access or use; and

(b) notify Vision of, and take all steps to prevent or stop, unauthorised copying, use or disclosure.

7.3 privacy

In performing its obligations under this agreement, the Licensee must comply, and use all reasonable efforts to ensure that its contractors comply, with all applicable legislation relating to privacy of personal information.

8 exclusions and limitations

8.1 acknowledgments

The Licensee acknowledges that:

(a) it has selected the Goods from a range of products and has satisfied itself that the Goods meet the Licensee's requirements;

(b) no oral or written information, representation or advice given by or on behalf of Vision, other than as contained in this agreement, creates a warranty or in any way increases the scope of this agreement; and

(c) unless expressly agreed otherwise in writing, the Licensee has not relied on any information, representation or advice given by or on behalf of Vision in selecting the Goods; and

(d) Vision makes no representation that the Goods conform to country, state or local laws, ordinances, regulations, codes or standards (except as may otherwise be agreed to in writing by Vision) and the Licensee is responsible for complying with all local laws relating to use of the Goods at its own cost.

8.2 exclusion of implied terms

Vision excludes from this agreement all conditions, warranties and liabilities implied or imposed by law or custom except any liability or implied condition or warranty the exclusion or limitation of which would contravene any statute or cause any part of this **clause 8** to be void (**'Non-Excludable Condition'**).

8.3 non-excludable conditions

To the extent permitted by law, Vision's liability for any breach of any Non-Excludable Condition is limited to:

(a) in the case of services, the resupply of the services or the cost of having the services supplied again (at Vision's option); and

(b) in the case of goods, the lowest of the cost of replacing the goods, acquiring equivalent goods or having the goods repaired.

8.4 exclusion of liability

To the extent permitted by law, Vision excludes all liability (including liability for negligence) for:

(a) any indirect or consequential expenses, losses, damages or costs (including, without limitation, loss of profits, loss of revenue, loss of or damage to data, failure to achieve anticipated savings or benefits, and any third party claims) incurred by or awarded against the Licensee under or in any way connected with this agreement or the use of the Software or Documentation;

(b) without limiting the foregoing, any expenses, losses, damages or costs incurred by or awarded against the Licensee arising directly or indirectly in respect of clinical (including without limitation diagnostic, prescription and other treatment) errors made while using, or otherwise associated with the use of, the Software or Documentation; and

(c) the operation or performance of, and any expenses, losses, damages or costs suffered or incurred by the Licensee as a result of its use of, any Third Party Material.

8.5 limitation of liability

To the extent permitted by law, Vision limits its total aggregate liability (including liability for negligence) for any damage arising under or in any way connected with this agreement or the use of the Software to the price paid by the Licensee for the Software or the Goods containing the Software under the Supply Agreement.

9 indemnity

The Licensee indemnifies Vision against all expenses, losses, damages and costs (on a solicitor and own client basis) incurred by or awarded against Vision arising directly or indirectly from or in relation to:

(a) any use of the Software not in compliance with this agreement;

(b) any breach of any Third Party Licence Terms by the Licensee;

(c) the Licensee's infringement of Vision's Intellectual Property rights;

(d) clinical (including without limitation diagnostic, prescription and other treatment) errors made while using, or otherwise associated with the use, of the Software or Documentation;

(e) any failure by the Licensee to comply with laboratory practices that are consistent with industry practice, laws, guidelines or decisions in the handling or use of the Software

(f) the Licensee's negligent acts or omissions; and/or

(g) any other use or misuse of the Software by the Licensee.

10 term and termination

10.1 term

This agreement commences on the Effective Date and continues until terminated in accordance with this agreement.

10.2 termination

(a) The Licensee may terminate this agreement at any time by destroying all copies of the Software and Documentation.

(b) The Licensee's rights under this agreement will terminate immediately without notice from Vision if the Licensee fails to comply with any provision of this agreement or if the Licensee does not strictly observe the terms of payment under the Supply Agreement, and on termination, the Licensee must destroy all copies of Software and Documentation in its possession or control.

10.3 accrued rights and remedies

Termination of this agreement under this **clause 10** does not affect any accrued rights or remedies of either party.

10.4 survival

Clauses 4 (intellectual property), **7** (confidentiality and privacy), **8** (exclusions and limitations), **9** (indemnity), **10.3** (accrued rights and remedies), **10.4** (survival), **11** (force majeure) and **12** (general) continue after termination of this agreement.

11 force majeure

Neither party will be liable for any delay or failure to perform its obligations pursuant to this agreement (other than on obligation to pay money) if that delay is due to Force Majeure. If a delay or failure of a party to perform its obligations is caused by or anticipated due to Force Majeure, the performance of that party's obligations will be suspended. Either party may terminate this agreement if a Force Majeure persists for a continuous period of 90 days.

12 general

12.1 severance

Part or all of any provision of this agreement that is illegal or unenforceable may be severed from this agreement and the remaining provisions will continue in force.

12.2 entire agreement

This agreement (including any additional terms notified to the Licensee by Vision) constitutes the entire agreement between the parties and supersedes any prior representations, warranties, understandings or agreements that relate to the same subject matter.

12.3 variation

This agreement may only be amended by agreement in writing between the parties.

12.4 governing law

This agreement is governed by the laws of the State of Victoria, Australia, and the parties submit to the non-exclusive jurisdiction of the courts in that State.

contacting vision biosystems

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You can also visit the Vision BioSystems Web site: http://www.vision-bio.com

revision record

Rev.	Issued	Sections affected	Detail
A01	Aug 2003	All	First release
B01	Nov 2004	All	Combined Bond-x information into this manual; Changes to slide identification.
C01	Mar 2005	All	Revised for Bond V3.03 software.
D01	Jun 2005	All	Revised for Bond V3.03A software.
D02	Sept 2005	Chapter 8 Chapter 11	Reagent identification text corrected. Refine detection system added.
E01	May 2006	All	Revised for Bond V3.04 software.
F01	Sept 2006	6.1.9 Delayed start 9.3.5 Reagent usage report 10.1 Date & time selector	Revised for Bond V3.4A software.

regulatory notices

FCC compliance

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference, and
- This device must accept any interference received, including interference that may cause undesired operation.

FCC class B compliance statement

This equipment has been tested and found to comply with the limits for a Class B digital device pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio or television technician for help.

CE marking and european union notice

CE The CE mark on the equipment indicates compliance with the In Vitro Diagnostic Medical Devices Directive (98/79/EC) and the Electromagnetic Compatibility Directive (89/336/EEC). Marking of equipment in this manner denotes that the equipment meets the following technical standards:

IEC 61010-1	"Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1 General requirements"
IEC 61010-2-010	"Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2 Particular requirements for the heating of materials"
EN 61326	"Electrical equipment for measurement, control and laboratory use – EMC requirements"
EN 55011	"Limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific and medical (ISM) radio-frequency equipment" – Class B
EN 61000-3-2	"Limits for harmonic current emissions (equipment input current < 16A per phase)"
EN 61000-3-3	"Limitation of voltage fluctuations and flicker in low-voltage supply systems for equipment with rated current < 16A"
EN 61000-4-2	"Electrostatic discharge immunity test"
EN 61000-4-3	"Radiated, radio-frequency electromagnetic field immunity test"

EN 61000-4-5	"Surge Immunity Test"
EN 61000-4-6	"Conducted disturbances induced by radio frequency fields, immunity test"
EN 61000-4-8	"Power-frequency magnetic field immunity test"
EN 61000-4-11	"Voltage dips, short interruptions and voltage variations immunity test"
ISO 13485: 2003	"Medical Device-Quality management systems-Requirements for regulatory purposes"

A "Declaration of Conformity" in accordance with the preceding directives and standards has been made, and is on file at Vision BioSystems, 495 Blackburn Road, Mount Waverley, Victoria 3149, Australia, and Vision BioSystems (Europe) Ltd, Ballilol Business Park, West Benton Lane, Newcastle upon Tyne, NE12 8EW, United Kingdom.

safety

UL Canada:	CAN/CSA C22.2 No. 1010-1
UL USA:	UL 61010A-1, First Edition
Europe:	IEC 61010-1 IEC 61010-2-010
UL Listed	File N° E177955-V1-S4
	To maintain compliance with the above Rules and Regulations, use only the cables supplied with the equipment.

safety

The Bond™ system is designed to provide trouble-free and safe operation when used in accordance with this documentation.
To keep the system in peak condition, follow the instructions given in Chapter 12 "cleaning and maintenance", and use only replacement parts supplied by Vision BioSystems™ or an approved provider.

biological and chemical hazards

Some of the reagents used in immunohistochemistry and in situ hybridization are hazardous, for example some chromogen reagents are potential carcinogens. When working with the Processing Module or components, including reagents or reagent containers, use precautions appropriate for handling of potential biohazards including the wearing of protective gloves and protective eye wear.

Warning
Be careful when opening reagent containers. It is possible that reagent may collect around the lid during transit and storage, and this may cause droplets of reagent to be flicked out when the reagent container lid is opened. You should always wear approved eye protection, gloves and approved protective clothing when handling reagents and reagent containers.

Clean spills with 70% alcohol. Do not allow xylene, chloroform, acetone, strong acids (like 20% HCl), strong alkalis (like 20% NaOH), or other similar solvents near the Processing Module. Immediately clean any spills of these materials from the Processing Module.

Bond-max Do not use xylene or other alternatives as dewax solution, as this has the potential to degrade some parts of the Bond system, which in turn may lead to fluid leakage.

During operation of the Bond system, some reagents (including potentially hazardous reagents) may collect around the Slide Staining Assemblies. This has the potential to contaminate slide trays as they are inserted and removed from the Processing Module, and this in turn has the potential to contaminate the preparation tray (if used). Whilst the risk of adversely affecting the surrounding environment and personnel is considered minimal, users should wear protective clothing, including adequate gloves, whilst handling slide trays and preparation trays.

Users must be aware of local regulations and correct procedures at their site when handling and disposing of hazardous material.

mechanical hazards

Bond-max Slide Staining Assemblies in the Bond-max may be very hot and cause severe burns. Do not touch the slide staining assemblies or their surrounds within ten minutes of cessation of operation of a Processing Module.

During operation the Processing Module uses an aspirating probe, which is positioned by a moving metal robotic mechanism.
Both the arm and the aspirating probe may move without warning, and with a speed that may cause injury.

The Processing Module includes interlocks that stop operation when the lid is open. You should not attempt to open the lid while a run is in progress, nor should any attempt be made to by-pass the interlocks.

The Processing Module is very heavy and is not designed to be moved by the user.
You should contact an approved service representative if you need to re-locate your system.

Always be careful to use undamaged slides, and ensure that slides are correctly aligned on slide trays before loading into the Processing Module.

Before operating your Bond system, close the syringe cover.
It is possible that if the syringe or the syringe fittings become loose, that some reagent under pressure may spray from the syringe. Closing the syringe cover will prevent escape of reagent in the unlikely event of this occurring.

electrical hazards

Dangerous voltages are present inside the Bond Processing Module. Only service technicians approved by Vision BioSystems should remove any of the Processing Module covers or access the internal components of the Processing Module.

The Processing Module's operating voltage is set during installation and initial set up, and must not be changed except by qualified service personnel.
The Processing Module must be connected to an earthed mains power outlet socket, and be positioned so that personnel have easy access to the power connection to the Processing Module.

In the unusual circumstance that the Processing Module supply voltage is to change, contact a service representative to have the setting changed.
Severe damage may occur if the Processing Module is connected to an incorrect power supply voltage.

warnings and cautions

A warning triangle means: "Attention. Consult the appropriate documentation or accompanying text before proceeding. Personal injury or damage to the system may occur if correct instructions are not followed." Warnings and cautions appear both on the equipment and in the documentation, where appropriate.

Warning
Warnings alert you to possible death or injury that may result from some action relating to the equipment.

Caution
Cautions alert you to possible damage to, or failure or malfunction of, the equipment or other property as a result of some action relating to the equipment.

The following symbols are used in the Bond system and or documentation:

Possibility of hand or body part being crushed.
Do not operate equipment with lid open or insert fingers inside the equipment.
Do not attempt to by-pass the interlocks.

Hot surface. Touching may cause burns.
Avoid touching parts identified with this symbol.

Hazardous fluids. Always wear protective clothing and gloves.
Immediately clean up spills using standard laboratory practice.

Laser hazard. Potential for severe eye damage. Avoid direct eye contact with laser beams.

Potential of contamination or infection by biohazardous materials.
Avoid unnecessary contact and observe the procedures specified at your site for handling of potentially biohazardous material.

Electrical hazard. Do not remove covers on the equipment other than as specified in the accompanying documentation.
Before changing fuses, turn the equipment off and disconnect the power cord.

Toxic hazard. There is a danger of severe health impacts if proper chemical handling procedures are not followed.
Use gloves and protective eye wear when handling reagents.

contents

1

welcome

Congratulations on obtaining your Bond™ system—you now have the latest in a series of instruments designed and manufactured by Vision BioSystems™.

The Bond system automates advanced staining processes including IHC and ISH (Bond-max only). Once the correct protocols and tests are selected, you have only to decide on reagents and make appropriate dilutions.

Each Bond system consists of a central host computer and up to five Processing Modules. There are two Processing Module types available—Bond-x and Bond-max—with each having a 30 slide capacity.

To avoid contamination of reagents and slides, the instrument should be operated in a clean environment as free as possible from dust and particulate matter.

The Bond system is the result of an extensive research program to provide an innovative stainer that meets the requirements of the modern laboratory. It features:

- High throughput
- Flexibility
- Safety
- Automated IHC staining and counterstaining (Bond-x and Bond-max)

Bond-max

- Automated ISH staining and counterstaining (Bond-max only)

Bond-max

- Automated dewaxing, baking and retrieval (Bond-max only).

Slide tray batches of up to ten slides can be loaded into Bond while other batches are in progress, providing continuous batch processing and leading to high throughput.

The flexibility of Bond also permits simultaneous processing of slide racks using different staining protocols, so that different types of staining can be conveniently performed at the same time without reprogramming or reagent changes.

Bond incorporates features that ensure high flexibility, convenience, and above all, quality staining. The outstanding flexibility, throughput and quality staining capability of Bond has set a new standard in staining excellence.

We trust that you will find the Bond system a valuable addition to your laboratory.

1.1 getting help

The Bond software includes an on-line Help system, that contains a search facility so you can easily find the information you want. To start the Help system, select "Help topics" from the Help menu or press the **F1** key from any screen to launch the help system at the topic most relevant to the current Bond operation. Refer to "bond help" on page 56 for detailed Help system instructions.

For problems with your Bond system, you can get assistance from your local representative, or contact us via the Vision BioSystems' Web site: http://www.vision-bio.com.

Contact information is also included in "contacting vision biosystems" on page 9.

1.2 conventions used in this document

As you read through this documentation we have used the following formatting to help make it clear what is being described or required. For example, in a procedure you may be asked to press the F1 key on the keyboard. In this case the document will read "Press the **F1** key"

Name	Attributes	Example
Key press or button	Bold	**F1, k, PgUp, OK, Cancel**
Field or group names in software	Italic	The *Marker* field appears dimmed.
User input or selection	Quotation marks	Select "Negative Control" as the *Slide type*.

Bond-max Where ***Bond-max*** appears in the left-hand margin (as shown), the associated information relates only to the Bond-max Processing Modules.

1.3 work flow

This section describes the work flow for using your Bond system, and where to find information for each stage.

1.3.1 overview

Step	Description	Manual Section
1	**Installation and commissioning** Hardware set up, software installed, system checked. Performed by representatives of Vision BioSystems or associated distributors.	—
2	**Read the safety section** Become familiar with the safety requirements for the Bond system.	"safety"
3	**Know your hardware** Become familiar with the names and uses of the pieces of Bond hardware.	Chapter 2
4	**Know your software** Gain a general understanding of the software and how to use it.	Chapter 3 Chapter 4
5	**Check requirements** A default set of reagent details, reagent inventory, and protocols is set up during initial installation and commissioning. The reagents and protocols may have been set up for your site during installation. If you are not sure, then do the following: Check that the protocols you want to run have been set up. Check that you have the reagents that will be required for the protocols you want to run at your site.	 Chapter 8 Chapter 9
6	**Routine operation** For a very brief overview Quick start chapter.	 1.3.2 Chapter 5
7	**Advanced** As required, gain a more in-depth understanding of the software.	Chapter 6 to Chapter 10
8	**Working with a LIS** An optional package allows connection to a Laboratory Information System.	Chapter 11
9	**Looking after your Bond system**	Chapter 12

1.3.2 routine protocol runs

The following is an overview of the standard steps involved in staining a batch of slides using Bond. With different option settings other workflows are also possible.

Step	Description	Manual Section
1	**Initial checks** Perform initial checks when you start your Bond system, or at a scheduled time each day.	5.1,12.1
2	**Set up slides** 1. Create a case (or patient) on the Slide setup screen of the Bond software. 2. Enter details of the slides for each case. 3. Set up control slides. 4. Print slide labels and apply them to the slides. 5. Perform dewax and epitope retrieval if this is being done externally to Bond. 6. Print and review the Slide setup reports, to determine how to place the slides on slide trays. 7. Place the slides on slide trays and place a Covertile™ on each slide. 8. Load the slides into the Processing Module.	5.5, 7.4
3	**Load reagents** 1. Place the reagent containers into reagent trays. 2. Place the reagent tray in the reagent platform of the Processing Module. 3. Make sure all reagents have been read by reviewing the reagent area in the Status Screen.	5.6, Chapter 9
4	**Run protocols** 1. Press the **Load** button. 2. When the slides have been imaged, check that the correct details are displayed in the slides section of the Status screen (see "slide information" on page 107). 3. Click **Start** to run protocols on the loaded slides.	5.7, 6.1.7

Step	Description	Manual Section
5	**Unload the slides and reagents** 1. Press the unload button on the front panel of the Processing Module. 2. Remove the slide tray. 3. Remove the Covertiles from the slides, then continue with the slides according to your laboratory processes. 4. Remove the reagent tray(s) and store the reagents.	5.8
6	**Do end of run clean** 1. Clean the slide and reagent trays. 2. If necessary, clean around the Slide Staining Assemblies with 70% alcohol. 3. Check the Covertile clamp springs. 4. Check bulk containers.	Chapter 12

1.4 important tips for operating your bond system

We strongly recommend that you always run the Bond system with control tissue on the same slide as the sample tissue. In the unlikely event of a user error (such as accidentally putting the wrong slide ID label on a slide, or forgetting to use a Covertile) or an instrument error, this procedure will greatly reduce the risk of an incorrectly stained slide going unnoticed.

- When staining frozen sections, use a protocol that does not include hydrogen peroxide. Hydrogen peroxide can cause bubbling, which in turn affects staining.
- The system should not be left off for extended periods of time, however, we recommend that:
  - each processing module (PM) be power cycled (turn off, wait 30 seconds, turn back on) once every 24 hours. This cleans and primes the fluidics system.
  - the software is shut down daily. This clears accumulated buffers and leads to better long term operation of the software and better system performance.
- After running 2 slide tray batches continuously in the same Slide Staining Assembly, a "mixing station not available" attention icon may appear. This is standard operation, and indicates that the mixing station is being cleaned. Please wait for the mixing station to be cleaned before putting another batch onto the Processing Module.

2

hardware

This section is designed to tell you:

- Names of the pieces of equipment in the Bond™ system
- Functions of these items, and how they relate to the system as a whole
- Where to find further information, for example, operational procedures and maintenance procedures related to the equipment.

Details of how to set up and connect components are not included with the hardware descriptions, as the system should be set up and tested for you. If you need to replace or re-connect components, details are included in Chapter 12 "cleaning and maintenance".

2.1 the bond system

The Bond system consists of the following major components:

- Processing Module, where staining protocols are run on tissue samples mounted on slides. For information on the features of the Processing Module, see "processing module" on page 29.
- Computer, which controls the Processing Modules and connects the handheld ID scanner, Slide Labeller, and printer if one is installed. See "computer" on page 38.
  The computer is provided and is UL listed (either UL 60950 or UL 1950) as well as IEC 60950 certified.
- Handheld ID scanner (see "handheld ID scanner" on page 39).
- Slide Labeller, which produces the labels that Bond uses to identify slides (see "slide labeller" on page 40).
- To print reports you will also need a printer with a USB connection.

The Bond system includes the following ancillary hardware as part of the system:

- Bulk reagent containers (see "bulk containers cavity" on page 35)
- Bulk waste containers (see "bulk containers cavity" on page 35)
- Covertiles (see "vision biosystems covertiles" on page 42)
- Slide trays (see "slide trays" on page 43)
- Reagent trays (see "reagent trays" on page 43)
- Depending on the configuration of your system, you will also receive Vision BioSystems™ detection systems, reagent packages and open reagent containers.
- Refer to the Bond consumable items catalog for a complete and up-to-date list of consumable items and spare parts.

2.2 processing module

The Processing Module is the Bond system's staining platform. Each Bond system can include up to 5 processing modules in any mix of Bond-x and Bond-max types. After each module is switched on it goes through an initialization sequence before it becomes operational. This is explained in "processing module initialization" on page 30.

The following photos show the main Processing Module components. The numbered items are:

Nº	Name (Figure 1)	Section	Nº	Name (Figure 2)	Section
1	Lid	2.2.2	8	Aspirating probe	2.2.8
2	Robot arm	2.2.3	9	Wash block & Mixing station	2.2.9
3	ID imager	2.2.3	10	Reagent area	2.2.6
4	Slide Staining Assemblies	2.2.4	11	Syringe door	2.2.10
5	Level guide	2.2.5	12	Power switch	2.2.11
6	Front panel	2.2.6			
7	Bulk reagents cavity door	2.2.7			

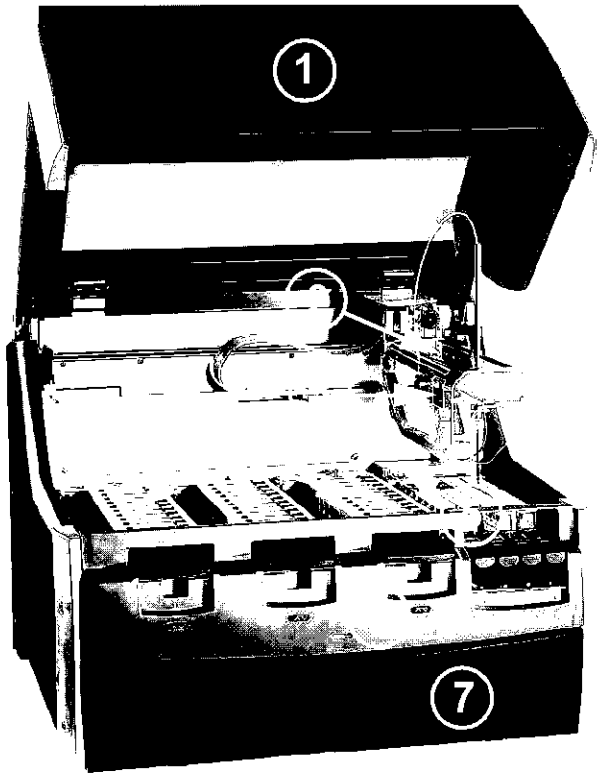


Figure 1: Front view of the Bond Processing Module

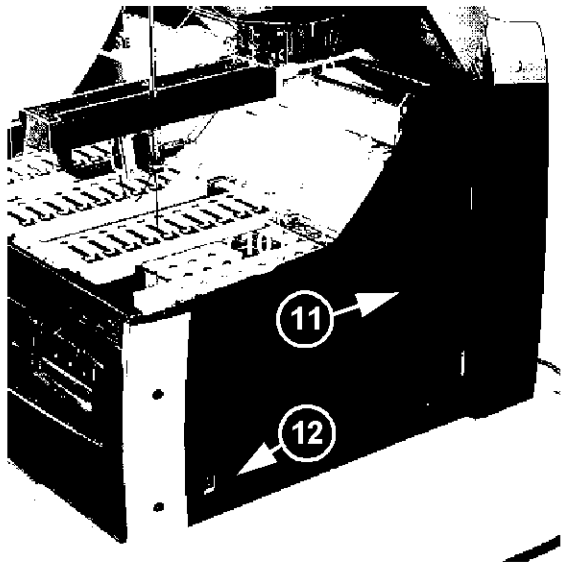


Figure 2: The Bond Processing Module viewed from the right side

During normal operation it should not be necessary to access any of the components on the back panel of the Processing Module. If you need to replace fuses or disconnect the Processing Module from the mains power supply, refer to "back panel" on page 222.

Locate the Processing Module so that either the mains wall outlet or the Processing Module's appliance inlet socket is accessible. Users must be able to disconnect the mains power cable without moving the Processing Module.

2.2.1 processing module initialization

When you turn the Processing Module on, the Bond system performs internal checks, primes the fluidics system and moves the robot to the home (back left) position. In addition, the Slide Staining Assemblies will initialize and return to their unlocked position. The initialization process will halt if a fault is found or if the module is in a state unsuitable for processing. Before attempting to initialize a Processing Module, check the following items:

- Check that the aspirating probe is up
- Ensure the lid and front door are closed
- Ensure the bulk waste bottles are not full
- Ensure the bulk reagent bottles are not empty
- Ensure the mixing station is in place
- Ensure the mixing vials are empty.

Caution
Before turning the Processing Module on, always check that the aspirating probe is up.
If the aspirating probe is down when the Processing Module is powered up, there is a risk that the robot may move before the probe is up, thus potentially damaging the probe.

Once the initialization process is complete the power LED on the front of the Processing Module will turn green and the Bond software will indicate that the module is connected. Do not attempt to use a Processing Module until it is fully initialized.

2.2.2 lid

The lid is designed to be closed during operation, and is protected with an interlock.

Warning
During operation the Processing Module uses an aspirating probe, which is positioned by a moving metal robotic mechanism. Both the arm and the aspirating probe may move without warning, and with a speed that may cause injury.

The Processing Module includes interlocks that stop operation when the lid is open. You should not attempt to open the lid while a run is in progress, nor should any attempt be made to by-pass the interlocks.

2.2.3 robot and ID imager

The robot positions the aspirating probe to aspirate and dispense reagents. The robot arm holds the ID imager, which is used to identify the slides and reagents loaded in the PM.

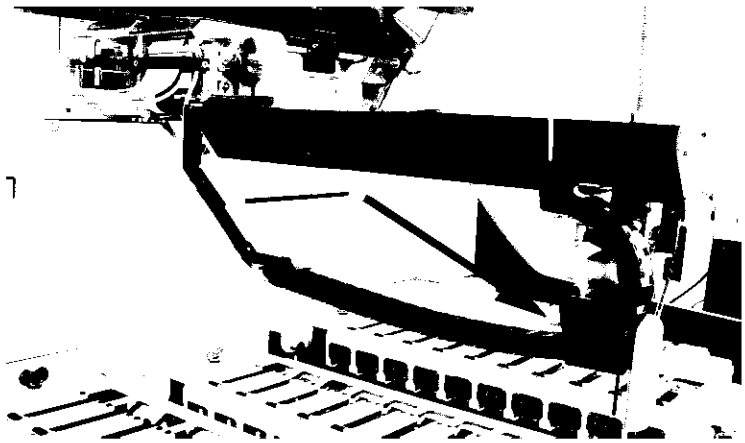


Figure 3: Photo of the robot with the ID imager indicated by the arrow

For slides, the Bond system captures an image of each label then runs a recognition process to identify each slide (see "automatic slide identification" on page 108).

- The ID imager window should be periodically cleaned.
  See "robot arm and ID imager" on page 214 for instructions.
- If the aspirating probe is broken or bent, replace it according to the procedure in "aspirating probe" on page 206.

2.2.4 slide staining assemblies

Bond-max

Warning

Slide staining assemblies in the Bond-max may be very hot and cause severe burns. Do not touch the slide staining assemblies or their surrounds within ten minutes of cessation of operation of a Processing Module.

Warning

During operation of the Bond system, some reagents (including potentially hazardous reagents) may collect around the Slide Staining Assemblies. This has the potential to contaminate slide trays as they are inserted and removed from the Processing Module, and this in turn has the potential to contaminate the preparation tray (if used). Whilst the risk of adversely affecting the surrounding environment and personnel is considered minimal, users should wear protective clothing, including adequate gloves, whilst handling slide trays and preparation trays.

Slides are processed in the Slide Staining Assemblies. Each Processing Module contains three Slide Staining Assemblies.

To begin a run, an operator inserts a slide tray through the front panel (described in "front panel" on page 34), then presses the load button. Bond will capture images of the slides. If the slides are compatible (refer to "fixing incompatible slide setup" on page 111) and all reagents are present, the user can then start the protocol. For more information about entering slide details and loading slides, see Chapter 7 "slide setup".

During processing, Bond locks the slides into the Slide Staining Assembly. Do not try to remove a slide tray while Bond is operating—abandon the run first.

User-maintainable components of the Slide Staining Assemblies are the top plate and Covertile™ clamps, which help position the slide and Covertiles in the Slide Staining Assembly. For cleaning and routine maintenance of the Slide Staining Assembly, see "slide staining assembly" on page 208.

slide staining assembly heaters

Bond-max Bond-max instruments have a heating element at each slide position. Each of these elements is independently monitored and is marked as faulty if a temperature error occurs (see Figure 4). Contact your service organization if a faulty heater is indicated.

Figure 4: Individual heater error

You should not attempt to run a slide that requires heating at a position marked as faulty. If a heater malfunctions during a run then the slide at that position is not processed correctly. If the heater malfunction is a potential safety risk, the Processing Module turns off all slide heaters, including the heater of any temperature controlled slide currently processing.

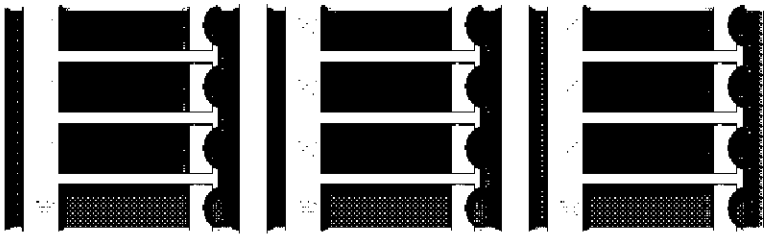


Figure 5: Grey heater symbols at each position indicate a complete heating shutdown

Once slide heating is shut down, you must turn off then restart the Processing Module to clear the heater lock. Be sure that you do not use the faulty heater position until it has been repaired.

You can continue to use slide positions with faulty heaters so long as the slides processed there do not require heating.

2.2.5 level guide

Levelling the Bond instrument is not critical for correct operation. While this guide provides a level indication, Processing Module operation will operate successfully even when the level indicator is well outside the central area of the guide.

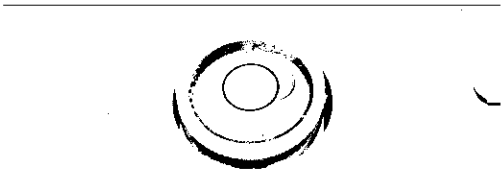


Figure 6: Level guide

2.2.6 front panel

Figure 7: Front panel

N°	Item	N°	Item
1	"power LED"	4	"load/unload button"
2	"slide tray bay"	5	"reagent platform"
3	"slide tray LED"	6	"reagent tray LED"

These items are described in the following sections.

power LED

This is located in the middle of the front panel, and operates as follows:

- Off: no power
- Orange: power on, but Processing Module software has not yet started
- Green: power on, system operating.

slide tray bay

There are three openings (one for each Slide Staining Assembly) where slide trays are inserted. When the slide trays are fully inserted, you can press the Load/Unload button to lock the tray into the Slide Staining Assembly. After locking the tray, the Bond system will capture an image of the slide IDs on the slides as soon as the robot arm is available.

load/unload button

Pressing a Load/Unload button does the following:

- If a tray is not loaded, nothing will happen.
- If a tray is loaded and not locked, Bond will lock the tray, and when the robot arm is available, the ID imager will examine the slide IDs.
- If a tray is locked and the run has not started the tray will be unlocked.
- If a tray is locked and the run is finished, Bond will unlock the tray.
- If a tray is locked and a run is in progress, the Load/Unload button has no effect. You cannot unlock a tray until a run using that tray is finished or abandoned.
- If the Slide Staining Assembly is hot it will not open.

slide tray LED

These are multi-color LEDs that function as follows:

- **Off**—the slide tray is not loaded and locked.
- **Steady orange**—the tray is loaded and locked but processing has not commenced.
- **Flashing red**—the batch has been rejected.
- **Steady red**—the batch is being processed.
  The tray will be locked and should not be accessed.
- **Flashing green**—processing is finished and the slide tray is still locked.
  The batch may have processed successfully, with errors or it may have been abandoned.

reagent platform

This is where reagent trays containing 7 mL and 30 mL containers are placed.
Each tray can hold up to nine reagents, and the reagent platform can hold four reagent trays.

To load a reagent tray, slide the tray onto the platform and into the locking mechanism (see "loading the reagents" on page 95). When the robot arm is available Bond will identify the reagents in each reagent position.

reagent tray LED

Below each tray position there is a bi-color LED that functions as follows:

- **Off**—a tray has not been detected.
  If a tray is inserted and the LED is off, check that the tray is inserted correctly.
- **Steady red**—a reagent on the tray is required within the next two minutes.
  The tray is locked and cannot be removed.
- **Steady green**—none of the reagents on this tray are required within the next two minutes.
  The tray is unlocked and may be temporarily removed.

2.2.7 bulk containers cavity

Bulk reagent and waste containers are located behind the door below the front panel.
The door is held by magnetic latches at each side of the door. To open the door, gently pull at the top of each side of the door. The software will display an alert if the door is open.

The bulk container cavity door should remain closed during staining runs.
If the door is open and the Processing Module needs to flush waste fluid to a bulk waste container, all current runs will immediately pause.

There is space for the following containers, in order from left to right:

Container	Processing Module types	Size (L)	Color	Reagent
Bulk waste	Bond-x	4	Gray	Standard waste
Hazardous waste	Both	2	Brown	Hazardous waste
ER1	Bond-max	1	Purple	Bond Epitope Retrieval Solution 1
ER2	Bond-max	1	Purple	Bond Epitope Retrieval Solution 2
Dewaxing solution	Bond-max	2	Red	Bond Dewax Solution
Deionized water	Both	2	Blue	Deionized water
Wash buffer	Both	2	Green	Bond Wash Solution
Alcohol	Bond-x Bond-max	2 2	Orange Orange	70% ethanol 100% ethanol

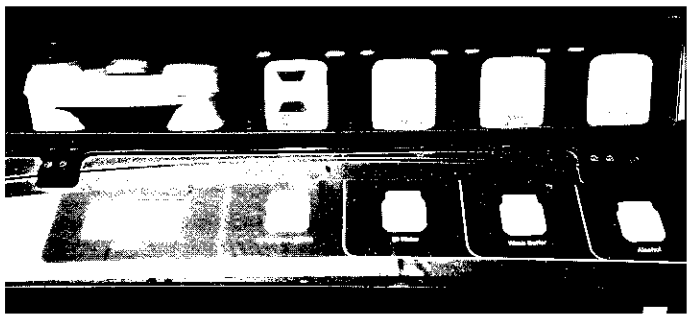


Figure 8: Bond-x bulk reagents in position

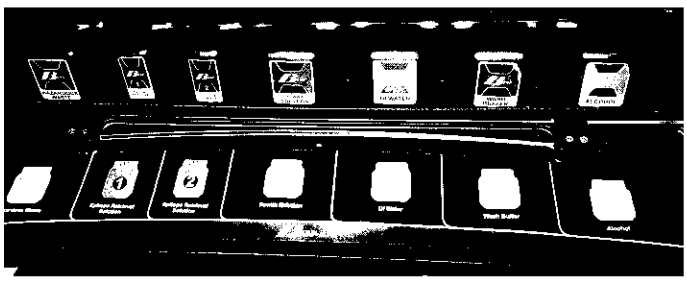


Figure 9: Bond-max bulk reagents in position

A 9 liter external waste container to collect bulk waste is standard on the Bond-max, and can be fitted to a Bond-x as an optional extra. This must be installed by a service representative. The external waste container has a grey label.

Bulk reagent containers contain liquid level sensors to warn when the reagent level is low; waste and hazardous waste containers also have a liquid level sensor that sense when the waste level is too high.

To avoid reagent spills, staining runs will be abandoned if a waste liquid level warning is activated during a run.

Ensure that the bulk containers are in the correct state at the start of each day: empty bulk waste containers and fill bulk reagent containers. Ensure that bulk containers are in place before operating the Processing Module. The Processing Module will pause operations if containers are missing.

If an external waste container is fitted, ensure the cap is firmly fitted before operating a Processing Module. If the cap is not firmly fitted, it is possible that in the unexpected case of the level sensor failing that waste liquid may leak or spray from the container. For more information, see "external waste container" on page 44.

Waste from the chromogen and dewax steps of a protocol is sent to the hazardous waste container; other waste is sent to the bulk waste container.

"bulk containers" on page 213 describes how to maintain bulk containers.

2.2.8 aspirating probe

The aspirating probe aspirates reagents from containers, delivers reagents to the slides in the Slide Staining Assemblies, and mixes chromogens in the mixing station. It contains a Liquid Level Sensor to detect reagent level (refer to 9.1.3"determining reagent volume" on page 157). There is a residual volume in each container that the probe is unable to reach. This volume is referred to as the "dead volume". Dead volume is different for each type of container.

"aspirating probe" on page 206 describes how to replace the aspirating probe.

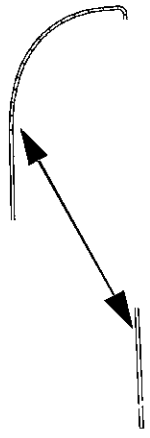


Figure 10:
Diagram of the aspirating probe (indicated by arrows) installed in the robot arm

2.2.9 wash block and mixing station

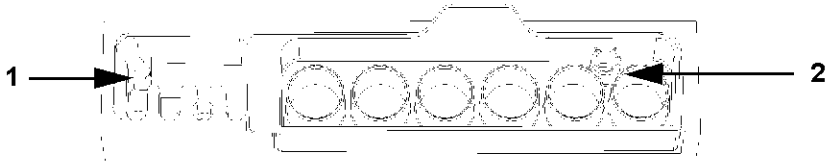


Figure 11: Wash block with mixing station inserted
The wash area is at the left (item 1), and the mixing station is at the right (item 2)

At the left of the wash block, thin holes provide for aspirating probe wash and probe tip washing.

The right part of the wash block holds the mixing station, which consists of six cavities. These are mixing containers for short-life reagents that must be mixed just before use.
This is determined by the software and reagent type, and is done automatically when required.

The Processing Module will not initialize (start up) if there is liquid in any of the mixing station vials. This is to ensure the vials do not overflow during processing.

The mixing station contains an ID label that enables the Bond software to check if a mixing station is present. If the software cannot detect this ID, then a message will prompt you to confirm that a mixing station is present.

2.2.10 syringe door

This door (Figure 2 item 11) protects the syringe, which controls the aspiration and delivery of reagents.

Check the syringe at least weekly to ensure that air does not enter the fluid lines. Air entering the fluid lines may lead to inconsistent staining.

To check the condition of the syringe unit, open the door by pressing and releasing at the rounded tab in the front middle of the door. If there are leaks or damage in the unit, contact Customer Support for advice.

2.2.11 power switch

This is a single rocker switch located at the lower front of the right cover of the Processing Module. This is used to turn the Processing Module on and off.

2.3 computer

The host computer controls up to five Processing Modules, provides data storage, and provides the connection for the handheld ID scanner, the Slide Labeller, and standard printer, if installed. The computer is set up and connected to the Processing Module for you during installation of the Bond system.

Do not shut down the computer during a run.
To change the user that is logged on to the computer, use "Log off" from the operating system "Start" menu rather than turning the computer off.

The following ports are used for the Bond system:

- Serial: For connection of the handheld ID scanner (non-USB version)
- USB: For connection of the handheld ID scanner (USB version)
- Parallel: Used by the Slide Labeller
- Extra network connection: Connection to the Processing Modules
  This is the additional network card that is installed in the computer.

You can use the standard network port, which is located beneath the mouse connection, to connect to your network.

To use a standard printer, connect it to one of the USB ports.

The options table displays computer network information that may assist your service organization. Refer to "options table" on page 82 for options table details; the computer setup options are:

Section	Key	Value	Editable
Ethernet	Gateway		No
Ethernet	SubnetMask0	255.255.255.240	No

2.4 handheld ID scanner

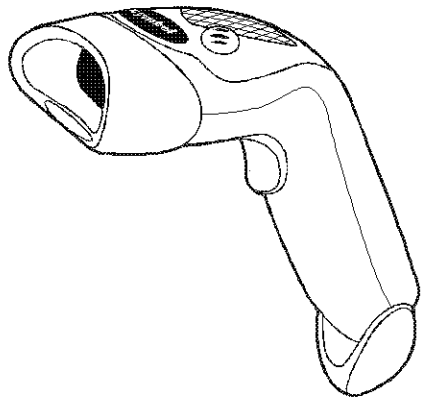


Figure 12: The handheld ID scanner

The handheld ID scanner is attached to the computer, and is used to register reagents. The handheld ID scanner should be installed and operational when your Bond system is installed.

The handheld ID scanner may be connected to either a serial or USB port on the host computer. If the ID scanner is replaced the ID scanner port setting may need to be altered. This will normally be done by your service organization but you may adjust these settings if required. Please refer to "ID scanner port settings" on page 74 for details.

2.4.1 using the handheld ID scanner

Caution
Laser hazard. Potential for severe eye damage. Avoid direct eye contact with laser beams.

To read an ID, point the window of the scanner to the ID, press and hold the trigger, and align the red line along the ID. The line should extend at least to each end of the ID.

The scanner beeps and the indicator turns green when an ID is recognized.
If the ID is not recognized the unit will beep repeatedly and the indicator on the top of the scanner will glow red.

Do not hold the ID too close to the scanner.
If the scanner does not recognize the ID, try moving the ID away from the scanner until it is recognized.

After a few seconds the ID scanner will turn off (unless it is in its holder). If this happens, release the trigger and start again.

2.5 slide labeller

The Bond system provides a unique slide identifier for every slide.
The Slide Labeller is used to print these unique identifiers onto slide labels, which are then put onto the slides. When the slides are loaded into the Processing Module the Bond software captures an image of the slide labels to identify the position of each slide. The Bond system currently supports two Slide Labeller types: the TLP3742 and the TLP3842 as shown below.

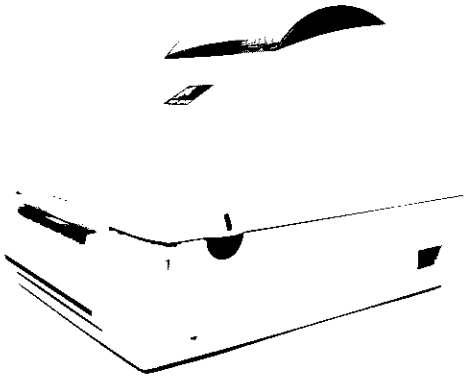


Figure 13: Slide Labeller — TLP 3742

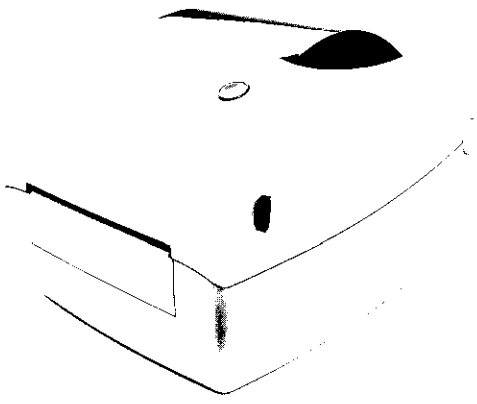


Figure 14: Slide Labeller — TLP 3842

The Slide Labeller is connected to the computer via a parallel port, and will have been installed and tested when your Bond system was installed. Use the documents supplied with the labeller for information on label and ribbon replacement, and cleaning.

To ensure the labels print correctly use only the "Bond Universal Slide Label".

2.6 ancillary equipment

This section describes the ancillary equipment that you may use with your Bond system.

2.6.1 slides

The area you can use for these slides is given in the following diagrams. The dispense volume refers to the settings you can choose when setting up slides using the Bond software (see "working with cases" on page 121).

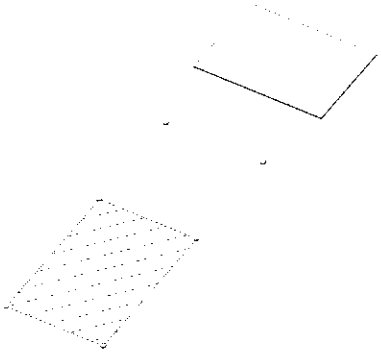


Figure 15: Bond-x 100 µL

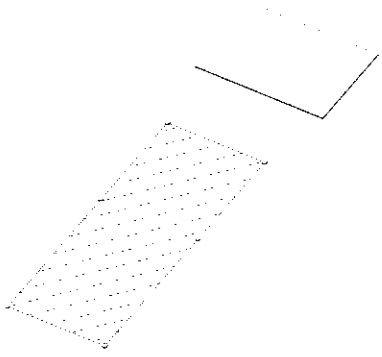


Figure 16: Bond-x 150 µL

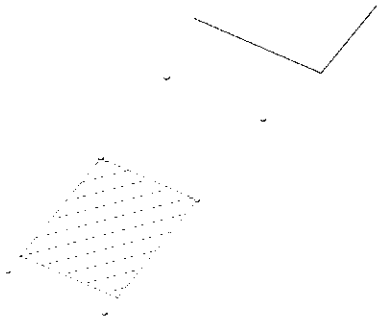


Figure 17: Bond-max 100 µL

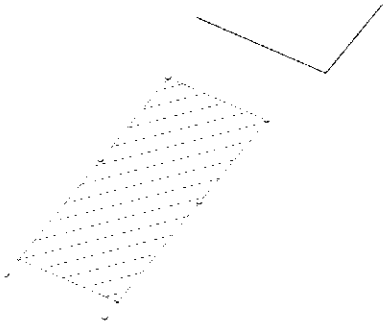


Figure 18: Bond-max 150 µL

Vision BioSystems™ Plus slides include markings that show the usable areas of the slide.

Vision BioSystems can provide slides for use with your Bond system. Please refer to the Vision BioSystems Product Catalog.

If you use your own slides, they must conform to the following specifications:

Dimensions	Width — 24.64–26.0 mm (0.97–1.02 in) Length — 74.9 – 76.0 mm (2.95–2.99 in) Thickness — 0.8 – 1.3 mm (0.03–0.05 in)
Label area	Width — 24.64–26.0 mm (0.97–1.02 in) Length —16.9 – 21.0 mm (0.67–0.83 in)
Material	Glass, ISO 8037/1

Caution
Do not use slides that have cut corners. These slides may fall through the slide tray and cause the Processing Module to abandon the batch.

2.6.2 vision biosystems covertiles

Use the Bond Universal Covertile for both Bond-x and Bond-max instruments.

Vision BioSystems Covertiles have been designed to optimize staining and are an essential part of the staining system.
You must place Covertiles on slides after placing the slides in the slide tray. The Covertile key must fit into the space in the slide tray.

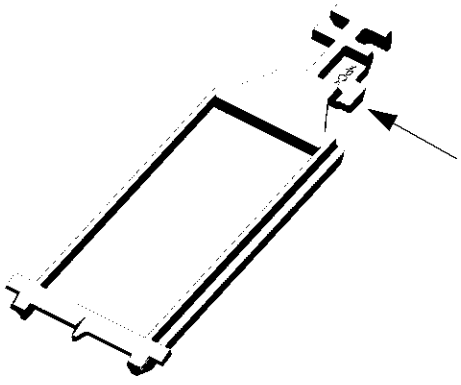


Figure 19: A Bond Covertile
The arrow indicates the Covertile key

The Covertiles can be reused up to 25 times provided they are not discolored or damaged, and provided they are cleaned properly. Discard damaged or discolored Covertiles.

Refer to "covertiles" on page 211 for details on cleaning and reusing Covertiles.

2.6.3 slide trays

Use the slide trays to hold slides and Covertiles in position when you load them into the Bond Processing Module. Each tray can hold ten slides.

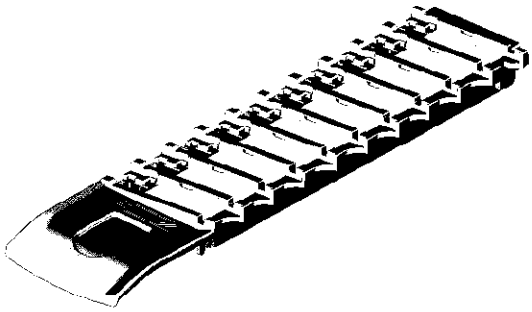


Figure 20: Slide tray

For instructions on loading slides and Covertiles into the Processing Module, see "loading slides" on page 94.

2.6.4 reagent trays

Reagent trays hold 7 mL and 30 mL Bond reagent containers, and the rack is placed in the Processing Module (see "reagent platform" on page 35).

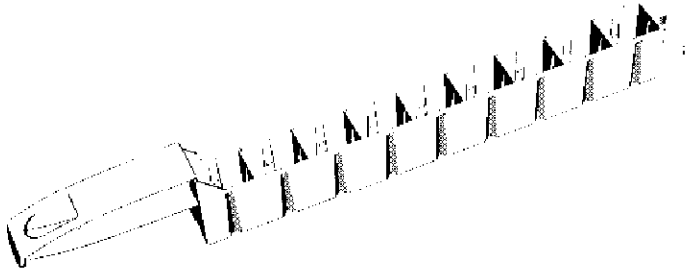


Figure 21: Reagent tray

Each reagent tray compartment has a groove which ensures that the reagent containers can be placed in the tray in only one orientation. This is important, as the ID on the top of the container must be placed in a specific position for the ID imager on the robot arm to capture an image of it.

For instructions on loading reagents into the Processing Module, see "loading the reagents" on page 95.

2.6.5 detection systems, reagents and open containers

Detection systems are predefined sets of reagents in a reagent tray. The reagent containers are sealed into the tray, and should not be removed. When the detection system is exhausted or expired, discard the complete tray and containers.

Bulk reagents are contained in **bulk containers** as described in "bulk containers cavity" on page 35.

Low volume reagents (such as primary antibodies and detection system components) use 7 or 30 mL containers that fit into the reagent racks.

Special purpose **titration containers** are also available (see "quality control" on page 230). These include a removable insert that allows the use of very small reagent volumes. The titration containers are available from Vision BioSystems as an aid to reagent optimization.

Open containers are empty, clean, containers for holding a user-supplied reagent (for example a primary antibody). Open containers can be used with one reagent only, and in some cases can be refilled with that reagent (see "refilling an open reagent container" on page 163 for details).

To use detection systems and reagents you must:

1. Register them (see "registering reagents and detection systems" on page 163).
2. Place all containers in reagent trays.
3. Open and secure the lids of all containers to the retainers on the rear of the container.

For instructions on loading reagents into the Processing Module, see "loading the reagents" on page 95.

2.7 external waste container

The 9 liter external waste container is supplied as a standard part of a Bond-max system, and is an option with Bond-x systems. It must be installed by a service representative.

Figure 22: An external waste container

If an external waste container is fitted, ensure the cap is firmly fitted before operating a Processing Module. If the cap is not firmly fitted, it is possible that in the unexpected case of the level sensor failing that waste liquid may leak or spray from the container.

The lid of the container has a waste fluid connection and a liquid level sensor connection. The fluid line connects to a push-fit connector at the bottom left of the lower rear cover of the Bond Processing Module, and the liquid level sensor connects to the upper right corner of the back of the Processing Module via a three-pin connector.

Inspect the external container regularly (at least every day), and empty it if it is getting near full. Before performing unattended runs or leaving the Processing Module on overnight, empty the external container to avoid overfilling.

When full, the external waste container is heavy.
Use correct lifting techniques when emptying the external waste container.

3

software overview

The Bond™ software, for use with Bond-x and Bond-max, uses standard Windows principles and methods of operation. In order to easily navigate and use the Bond system software you should be comfortable with using a mouse and standard Windows operations like using dialogs.

Because the Bond software is controlling important hardware and storing critical data, do not run other applications that consume virtual memory on a computer that is controlling a Processing Module. The software may shut down displaying an "OLE DB" error if other applications use too much virtual memory. Restart the Bond software if this occurs.

Do not shut down the computer during a run. To change the user that is logged on to the computer, use "Log off" from the operating system "Start" menu rather than turning the computer off.

This section is designed to help you become familiar with the software rather than use it to operate the system. For an example of preparing and performing a staining run, see Chapter 5 "quick start". This section describes:

The Bond software, like most Windows applications, uses the system settings for printing or reporting date and time. In some cases long date and time formats will exceed the space available for the date. To ensure that you do not lose information, set the short date format to a maximum of 12 characters and the long date format to a maximum of 28 characters.

3.1 system logon and access level

Before you are able to run the Bond software, you will need to log on to the host computer using a user name and password.

There are two Bond access levels available to laboratory staff: Operator and Supervisor. The access level is set by the Host computer logon. If your Windows system logon is a Power User account, the Bond software access level will be set to Supervisor; if your Windows system logon is a User account, the Bond access level will be set to Operator.

Supervisor access level enables all the features documented in this manual and a Supervisor can set up and remove logon accounts. The Operator access level limits the available functions to those required for setting up and running slide batches. The logon name is used to identify the person making any changes to protocols, slide properties, and other editable elements. The amount of logon information displayed can be configured from the options table (refer to "options table" on page 82). The options are described below.

Section	Key	Value	Description
UserName	UseDomain	0	Displays the logon name only
		1	Displays the network domain name along with the logon name

Each Bond system is supplied with two default logon accounts: one user account and one supervisor account. The laboratory supervisor will be supplied with the user names and passwords for these accounts when the system is installed. Laboratory supervisors (with a Power User account) can also create and manage new User and Power User accounts. For detailed instructions on account creation, please refer to "creating new logon accounts" on page 62.

3.2 starting the bond software

Once you have launched the Windows operating system using your user name and password, start the Bond software by double-clicking the Bond icon.
During installation, this icon was placed on the desktop of the computer operating system.

During startup the software displays the "splash" screen.

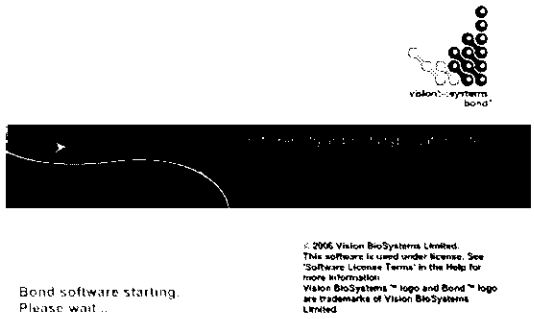


Figure 23: The Bond "splash" screen

When the software finishes the startup procedures it displays the Home screen. At the top and at the left of this screen there are features that are common to all pages of the software. The following section describes these features, and also describes general features of the software. Following that is a description of the major sections in the software.

Figure 24: The Bond software Home screen, with common features of the Bond software at the top and left of this screen

3.3 common features of the bond software

When you display screens in the Bond User Interface, they appear in place of the large rectangular area at the lower right of the Home screen. However, the following features will always be visible:

- "title bar"
- "menu bar"
- "function bar"
- "processing module tabs"

3.3.1 title bar

The Title bar is a standard Microsoft® Windows® Title bar: at the left it contains the application name (Bond), and at the right it contains Minimize, Maximize, and Close buttons. If you require more information about these items, please consult your operating system documentation.

3.3.2 menu bar

The menu bar is a standard Windows menu bar. Click on a menu item in the software to display the entire menu.

file menu

This menu allows you to exit the Bond software.

The Service logon function requires password access and is intended for use only by authorized service representatives.

window menu

Use the Window menu to display one of the Bond software screens.

item ID menu

The Item ID menu allows you to identify specific slides, reagent packages and detection system kits by entering the details on the item's identification label. This can be done automatically for the reagent packages and detection system kits using the handheld ID scanner, or manually for the slides, reagent packages or detection system kits, by entering in the number printed on the identification label.

- Select "Slide" from the Item ID menu to identify a slide (see "ad hoc slide identification" on page 129.
- Select "Reagent or detection system" from the Item ID menu to identify an individual reagent or an entire detection system (see "reagent identification" on page 156).

configuration menu

The Configuration menu allows you to set up and configure the following items:

Local settings

- Bond slide labels (and LIS slide labels for LIS-ip systems)
  Refer to "slide label configuration" on page 67
- ID scanner
  Refer to "ID scanner port settings" on page 74
- Audible warnings
  Refer to "sound setup" on page 74

System settings

- Doctors list
  Refer to "doctors list" on page 75
- Site preferences
  Refer to "site preferences" on page 78
- Processing Modules
  Refer to "processing module configuration" on page 80.
- Basic system options
  Refer to "options table" on page 82.

maintenance menu

The Maintenance menu facilitates syringe replacement and system cleaning (refer to Chapter 12 "cleaning and maintenance") as well as database backup (refer to "the bond database" on page 60).

help menu

From the Help menu you can display the on-line Help (select "Help topics") or you can display and report information about your Bond system (select "About Bond…"). These functions are explained in "bond help" on page 56.

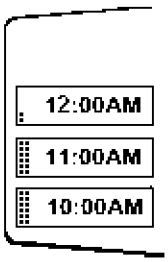
3.3.3 function bar

The function bar is located at the top of the Bond software screen, and provides quick access to the main sections of the Bond software. The icons are arranged on the function bar in order of the most commonly used sections of the software.

Click on an icon on the function bar to go to a screen as described in the following table. The software sections are more fully described in "main software sections" on page 53.

Icon	Screen displayed	Purpose
	Slide setup	Enter details of the slides to be run.
	Protocol setup	Edit and manage your protocols.
	Reagent setup	Work with reagent details or go to screens where you can work with reagent inventory or panels.
	Slide history	Display properties, run events, batch details, or service events for a slide.

3.3.4 processing module tabs



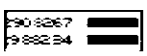
The software displays a tab at the left of the screen for each Processing Module installed. Each computer can run up to five Processing Modules, so you may see up to five of these tabs. These tabs are always visible while running the Bond software, and give a visual snapshot of the "processing module states". To display the detailed System status screen for a Processing Module, click on the tab. See "system status screen" on page 100 for more information.

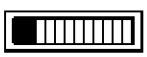
In normal operation these tabs will look similar to the one shown here. The Processing Module identification appears at the top, and the rectangular icons display the state of each Slide Staining Assembly installed in that Processing Module.

slide staining assembly states

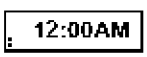
Before a run:


Blank rectangle: no tray present.

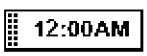

Animated ID numbers and solid bars: tray is being imaged.


Icon of tray with slides: slide labels have been imaged and the tray is ready to run.

During a run without errors:

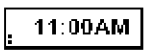


Time display in dark text: batch is running.
The time displayed is the estimated completion time for the batch.

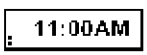


Flashing time display in dark text: the run is finished.

During a run with errors



Red time display: an error occurred, but the run is continuing.



Flashing red time: the run has finished, but an error occurred.

processing module states

If the software detects a Processing Module problem it will display an icon on the tab as follows:

Icon	Meaning	Icon	Meaning
	The Processing Module is not connected.		**Attention**: Bond has detected an error.
	The Processing Module is initializing or is not operating.		**Alarm** (flashing): To continue operation the Processing Module needs user intervention.

3.4 notifications, warnings and alarms

The Bond system has three alert levels: notification, warning and alarm. Each alert is indicated by an icon that appears on the Status screen over or adjacent to the item subject to the alert message. A corresponding alert icon may also appear on the Processing Module tab to provide an indication irrespective of the currently visible screen (refer to "processing module tabs" on page 51).

Right-clicking an alert icon and selecting "Attention message" launches a dialog that details the alert condition. Alerts may also be broadcast by the host computer's audio message system (refer to "sound setup" on page 74).

Chapter 6 "system status screen" details the alert implementation for each sub-system. The three alert levels and their associated icons are described below.

Not all notifications or messages are displayed on the Processing Module tab, however they are all displayed on the "Status" page of the software. Please check the status page to ensure that you see all messages and take appropriate action.

Steady

Notification

- Prior to the start of processing, a component is in a different state than expected and requires attention before processing can begin.
- During processing, a component is in a different state than expected, however processing will continue on the current batch. No action is required and/or possible.

Steady

Warning

- Warning is used when **all** of the following occur:
  - A component is in a different state than expected, and
  - current slides may be affected, and
  - there is a user action required (and possible) to avoid adverse effects on the current slides.
- Warning is also used when **either** of the following occurs:
  - an action is required to avoid causing damage to the instrument or endangering safety
  - a fault condition prevents the instrument from completing its initialization.

Flashing

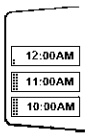
Alarm

- Alarm is used when **all** of the following occur:
  - A component is in a different state than expected, and
  - current slides may be affected, and
  - there is an **immediate** user action required (and possible) to avoid adverse effects on the current slides.
- Alarm may also be used when immediate action is required to avoid causing damage to the instrument or endangering safety.

3.5 main software sections

This section gives an overview of the major sections of the software.

Status screens



Status screens allow you to start running protocols on slides that are loaded into the Processing Module, and also tells you the current operational status of Processing Modules and protocols. These will be the most commonly used screens in routine operation along with the Slide setup screen.

To display the status screen for a Processing module, click on the tab at the left of the Home screen. (See "processing module tabs" on page 51).

Slide setup screen

This will be the most commonly used screen along with the status screens.
The Slide setup screen is where you enter the details of the cases, the slides for those cases, the control slides you want to run, and the protocols you want to run on the slides.
Protocols must be available for slide setup and a default set of protocols will have been installed when your Bond system was set up.

For more information see Chapter 7 "slide setup".

Protocol setup screen

This screen allows you to set up the protocols that you will want to run on slides, and view the protocols in the system.
Details of the reagents used in the protocols must be available before setting up protocols. A default set of reagents will have been set up during installation of your Bond system.

Click on the protocol icon in the function bar to display the Protocol setup screen.

For more information refer to Chapter 8 "protocols".

Reagent screens

These screens allow you to enter reagent details, register reagents, and work with reagent panels.

Before you can use reagent packages you must *register* them. Registering reagents is the process of adding physical amounts of reagent to inventory.
In order to register reagents, the details of the reagent must be available in the Bond software.
For information on entering reagent details and reagent registration, see "reagent management" on page 155.

Details of default reagents and registration of reagents will have been done during system setup. Click on the reagent icon in the function bar to display the Reagent setup screen. You can get to the other reagent screens from there.

History screens

The Slide history screen displays details of slides that have been run on the Bond system, and allows you to see details of individual slides as well as batch and case details. For more information refer to Chapter 10 "slide history".

3.6 using the bond software

This section describes some general principles for using the Bond software.

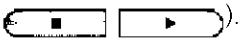
3.6.1 navigating

To move around in the Bond software, you can:

- Click an icon in the "function bar" (see "function bar" on page 50)
- Click one of the "processing module tabs" (described in "processing module tabs" on page 51)
- Select a screen from the "menu bar" ("menu bar" on page 49).

Some screens, for example the "reagent setup screen", have tabs at the top from which you can select related screens.

3.6.2 buttons

"Buttons" is a general term for software items that enable you to carry out commands by clicking on them. They include objects like **OK** and **Cancel** buttons and other buttons with icons that represent actions (simple examples being stop and start buttons ).

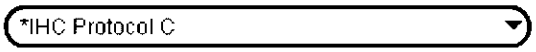
Sometimes buttons are dimmed. This means that they are not available for use. An example of this is when a slide tray batch is not loaded into a particular position. The buttons for starting and abandoning a protocol for that position are dimmed, and clicking on them has no effect.

3.6.3 selecting

You can select items from menus, and you can select icons and tabs to navigate through the software as previously described. You can also make selections using check-boxes, radio buttons, and drop-down lists, or you can select an item in a table:

- Click a **radio button** to select it 
  When a radio button has a colored center, it is selected.
  Where a group of radio buttons are placed together, you can select only one.

- **Drop-down lists** contain a number of items from which you can select.



  To select an item from a drop-down list, click on the down arrow to display the list, then select an item from the list.

- Click a **check box** to select it ☑
  When a check box contains a tick, it is selected.

  Where a group of check boxes are placed together, you can select more than one check box at the same time. An example is the panel antibody selection dialog.

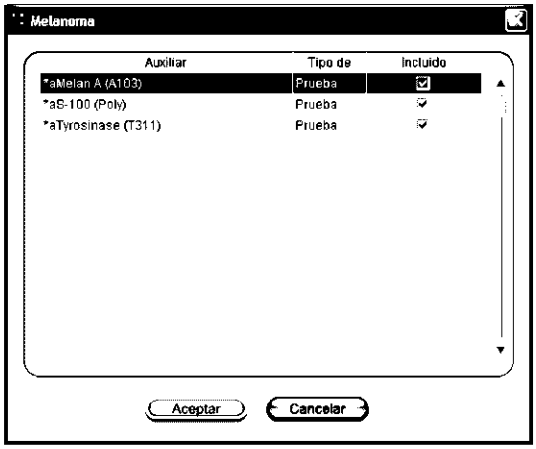


Figure 25: Panel antibody selection dialog

- When you click an item in a table, the background color changes to highlight it. This item is selected. You can also select items in some tables by pressing the arrow keys on your keyboard to move the highlight.
- In some cases we refer to right-clicking an item. This means using the secondary mouse button to click an item. In most cases the secondary mouse button is the right mouse button. If your mouse has been customized for left-handed use, it may be the left mouse button.
  Because Bond is a Windows application, we will follow Microsoft's convention of referring to the secondary mouse button as the right mouse button.
  Right-clicking is used to access submenus in the Bond software.

3.6.4 editing

Light areas are **editable fields**. These are the areas where you enter information.
To enter information in a blank field, click in the field and type the information. When entering information in fields in this way, do not press the **Enter** key, as this may submit a form or carry out an action before you are ready. To submit a form, click **OK**.

In some cases editable fields may contain default values that you wish to change. In this case, click and drag the cursor to highlight all of the text in the field, then simply type your own entry.

For entries that are larger than the field, you can use the Arrow, Home, and End keys on the keyboard to move within the field. Do not use the tab key, as in many cases this will move to another item on a screen.

Where the background of these fields are darker, these items cannot be selected or edited. An example of this is the View Protocols screen. This screen is provided as a safe alternative to displaying the Edit Protocols screen, and therefore you cannot edit any of the items on the View Protocols screen.

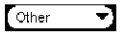


Figure 26: An editable field

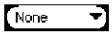


Figure 27: Field is not editable

3.6.5 sorting tables

Many screens in the Bond software display data in tables. Click on a table heading to sort by that field. An upward triangle ▲ appears beside the heading to indicate the table is being sorted in ascending order (0-9 A-Z). Click again to sort in descending order; the triangle points down ▼.

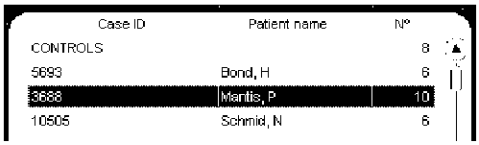


Figure 28: Click on a table heading to sort the table by that field (Patient name in this case)

3.6.6 shortcut menus

Some items in the software provide more detail when you right-click on them. These options will be described in the sections where they arise.

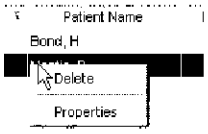


Figure 29: Right-click to display a submenu

3.7 bond help

The "Help" menu has two options: "Help topics", which provides a comprehensive guide to Bond operation; and "About Bond…", which provides system information, systems reports and allows the current system state to be sent to file to aid "fault" diagnosis.

3.7.1 using the bond help system

To launch the Bond Help system either:

- Select "Help topics" from the Help menu
- Press the **F1** key to launch the Help system at the topic most relevant to the current Bond operation.

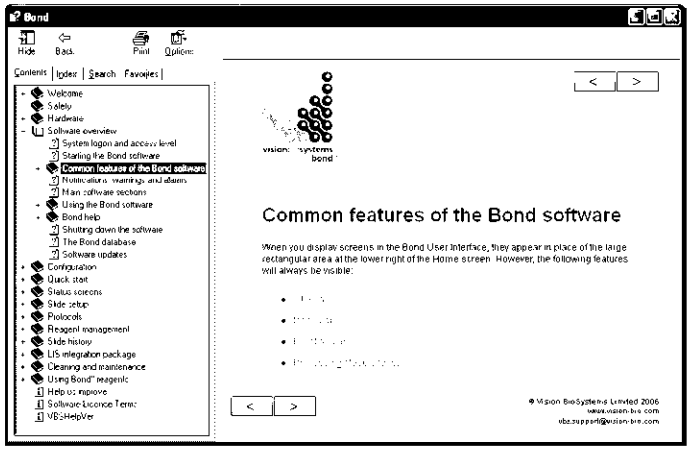


Figure 30: The Bond Help system

The Bond Help system uses the standard Windows Help format with a navigation pane on the left and the contents pane on the right. The navigation plane lets you select the contents in the following ways:

- Select the *Contents* tab to view a structured topic list. Clicking on the items displays the corresponding topic in the contents pane.
- Select the *Search* tab to initiate a keyword search. Enter the keyword in the *Type in the keyword to find:* field then select the required topic from the *Select Topic to display:* list. Click **Display** to view the corresponding topic in the contents pane.
- The *Favorites* tab allows you to create a list of commonly viewed topics. Select a topic to view then click **Add** to include the topic in the favorites list. Click **Display** to view a topic in the favorites list; click **Remove** to delete a topic from the list.

Navigation buttons [<] [>] on each contents page allow you to move forwards and backwards through the topics in sequence.

3.7.2 about bond

The "About Bond" dialog provides technical information relating to the state and configuration of the Bond system. It has a list of system information and includes a reporting function and a function that saves the current state of the instrument.

To launch the "About Bond" dialog, select "About Bond..." from the *"Help"* menu.

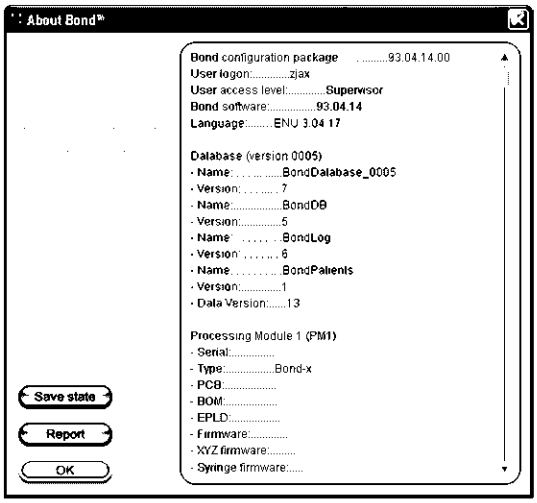


Figure 31: About Bond dialog

Much of the information in the About Bond dialog is principally of interest to service personnel, however laboratory staff may find the initial information group useful, especially during discussions with their service organization.

Bond software version:.....3.4A
Bond configuration package:.....93.04.84.00
User logon:.....jar
User access level:.....Supervisor
Bond build:.....93.04.84
Language:.....ENU 3.04.67

Figure 32: Initial information group

The information contained in the initial group is as follows:

- Bond software version — the principle release version number; a number to one decimal place, possibly with an appended letter.
- Bond configuration package — version number of the package of configuration files that support the main software
- User logon: — the name of the user currently logged onto the Bond system
- User access level: — the access level of the user currently logged onto the Bond system
- Bond build: — the version number of the main Bond software
- Language: — the current language and language version number.

saving system states

It is sometimes helpful to provide service personnel with a "snapshot" of the state of the Bond system to assist with problem diagnosis. This can be done from the "About Bond" dialog as documented in the following instructions.

1. Click **Save state** from the "About Bond" dialog.
2. Choose a location to save the file and enter the required name using the standard Windows "Save as" dialog.

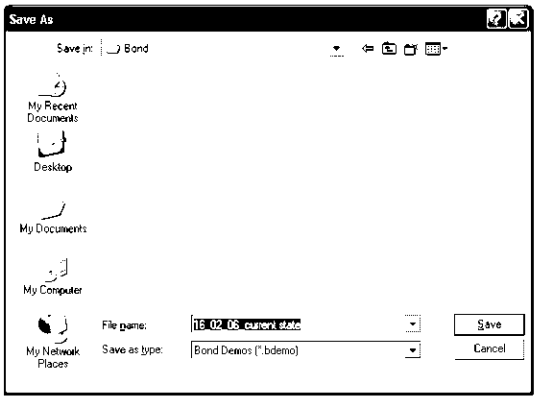


Figure 33: Windows Save as dialog

3. Click **Save** when you are happy with the details. The file will now be created in the directory you selected.

bond system report

The Bond system report contains the same information as that listed in the "About Bond" dialog. The report can be easily printed and saved using standard Windows functions. To generate the report, click **Report** from the "About Bond" dialog.

3.8 shutting down the software

To shut down the Bond software, select "Exit" from the *File* menu.

Shut the software down daily. This will clear accumulated buffers and lead to better long term operation of the software and better system performance.

3.9 the bond database

The Bond system uses a database to record all Bond data including case and slide details, reagents, and protocols. This data is critical for the correct operation of the system and if the database is lost or corrupted you will lose all slide and case histories as well as your protocols, reagent inventories etc. It is thus critically important that the database be well maintained and be backed up regularly.

The Bond software includes a database backup function that performs a number of important database maintenance tasks including creating a backup of the database files. It is important that you use the maintenance function regularly so that the database remains in good condition and so that you have a database backup. The function is also useful if you wish to create a database file to send to your service organization to aid fault diagnosis.

We recommend that you run the database backup function weekly or more frequently if you are processing a large number of slides. If you do not backup the database regularly you will receive a database warning message when you start the Bond system for the first time each day. You can configure the warning interval from the options table (refer to "options table" on page 82). The option table also shows the last backup date. The option details are shown below.

Section	Key	Value	Default	Editable
Backup	LastPerformed	Date of last backup	N/A	No
Backup	Regularity	The required interval (days)	14	Yes

Before you backup the database, make sure no batches are loaded or running and that no slide trays are locked on any Processing Module connected to the host computer. There will also be occasions where the backup function must close the Bond software: this will only happen very occasionally and you will be able to terminate the backup function before the shutdown. The backup function may take as long as 20 minutes to complete but is usually far quicker.

To initiate a database backup, select "Backup database" from the Maintenance menu. If prompted, confirm that you wish the software to close and the database backup to continue.

During the backup process a status dialog indicates the progress. Note that if the Bond software is still running this dialog may be behind the Bond software so you will need to select the backup process from the Windows task bar to view it.

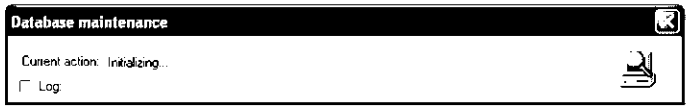


Figure 34: Backup progress dialog

Backup files are written to the following directory:

C:\Program Files\Vision BioSystems\Bond\DB\[Facility]_Backup

where "Facility" is the facility name given to the Bond system in the Site preferences dialog (Configuration menu, System submenu; see "site preferences" on page 78).

The backup files are cumulative so you do not lose any data by overwriting existing files.

We recommend that you copy the backup files to an external device such as a USB memory device or a network drive so that you have an off-instrument database backup.

If you wish to use these files to restore a lost or corrupted database, please contact your service organization who have the correct tools and knowledge to restore the database.

3.10 software updates

Vision BioSystems™ may release software updates as the Bond system continues to develop. The updates may be to the main software or to the database that contains the default protocols, reagents and detection systems. The new software may add additional functionality or new detections systems, reagents and protocols.

The version number of the current software version can be found in the "About Bond" dialog (refer to "about bond" on page 58). The database version is also displayed in the "About Bond" dialog as well as being displayed in the options table. The options table entry is shown below (refer to "options table" on page 82 for options table instructions).

Section	Key	Value	Editable
General	DataVersion	Current configuration database version	No

4

configuration

This chapter covers basic configuration options available for the Bond™ system. Most of these are accessed through the Configuration menu. However, "creating new logon accounts" below has Windows operating system settings, as has "report printer configuration" on page 79.

4.1 creating new logon accounts

Laboratory supervisors can create new Bond User and Power User logon accounts to allow staff to access the Bond system using their own identities (rather than using the single default logon). Please refer to "system logon and access level" on page 47 for logon details and use the following instructions to create new accounts.

1. Ensure no Bond batches are currently running or pending then close the Bond software.
2. Ensure a laboratory supervisor (with Power User access level) is currently logged onto the host computer.
   Log off, then logon as a supervisor if necessary.
3. From the Windows "Start" menu choose the "Control Panel" option.

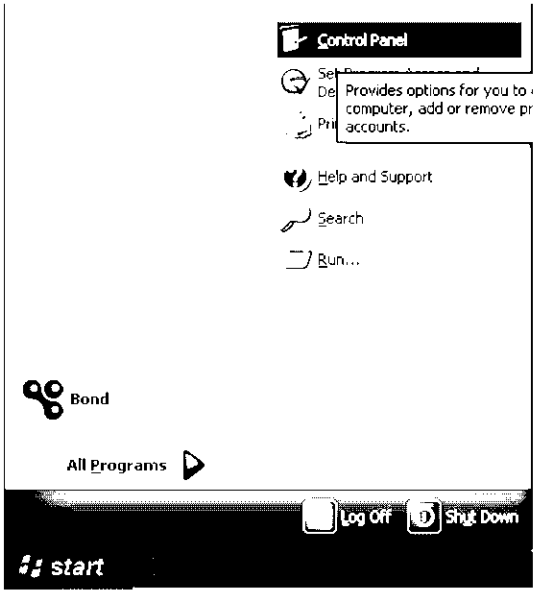


Figure 35: Launching the Control Panel

4. From the "Control Panel" window, double-click the "Administrative Tools" icon.

Figure 36: Administrative Tools icon

5. From the "Administrative Tools" window, double-click the "Computer Management" icon.

Figure 37: Computer Management icon

6. From the "Computer Management" window, double-click the "Local Users and Groups" entry.

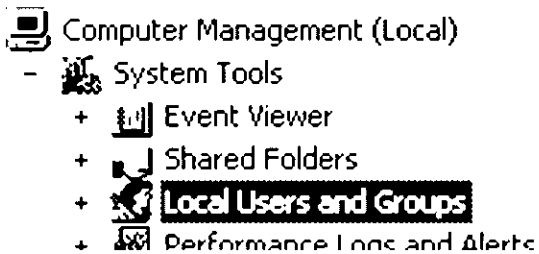


Figure 38: Local Users and Groups entry

7. Right-click the "Users" folder then select the "New User…" option from the shortcut menu.

Figure 39: New user from shortcut menu

8. From the "New User" window, complete the following fields and options:
   (i) Enter the logon name for the new user into the *User name:* field
   (ii) Enter the user's full name into the *Full name:* field (optional)
   (iii) Enter a description for the new account into the *Description:* field (optional)
   (iv) Enter the user's password into the *Password:* field (case sensitive)

(v) Confirm the password by re-entering it in the *Confirm password:* field (case sensitive)

(vi) Set the "Password never expires" option

(vii) Leave the other options unchecked.

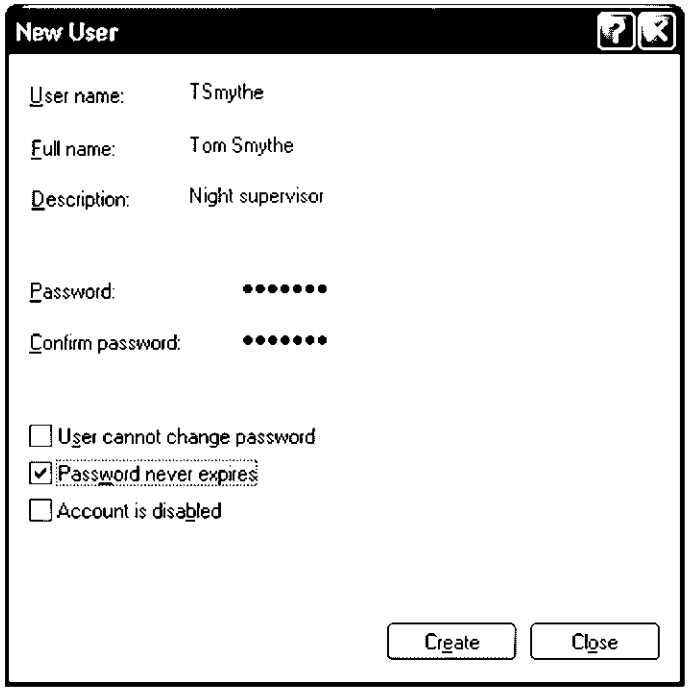


Figure 40: New User dialog

9. Click **Create** when all details are complete.
10. Enter new details for additional users and click **Close** when all additional users have been added.
11. The process to this point has created a new user (or users) with User level access.
    (i) If User level access is sufficient for the new accounts then close the "Computer Management" and "Administrative Tools" windows to finalize this procedure. The new accounts will be available at logon time.
    (ii) Continue with the remainder of these instructions to give an account supervisor (Power User) access.
12. From the accounts list (right pane of "Computer Management" dialog), double-click the account you wish to have supervisor (Power User) level access.

13. From the account properties window, select the "Member of" tab.

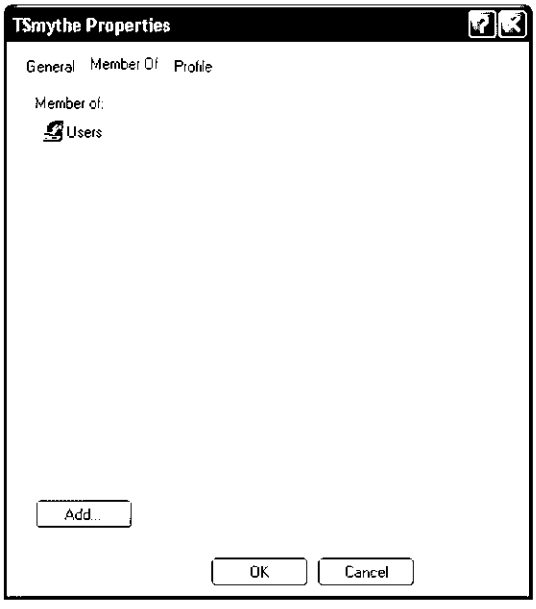


Figure 41: Account properties window with Member of tab selected

14. The "Member of:" list displays the account level groups that the current account is a member of.
    New accounts are automatically members of the Users group, other groups must be added if higher level access is required.
15. Click **Add...** if you wish to add Power User access to the current account.
16. From the "Select Groups" window, click **Advanced**.

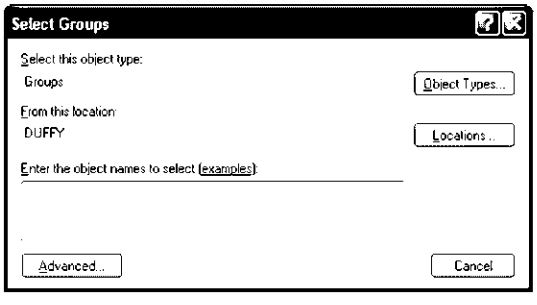


Figure 42: Select Groups window

17. Click **Find Now** from the expanded "Select Groups" window to list the access level groups registered on the system.

Note that although a range of access level groups are available, only Users and Power Users have any effect on Bond operation. Other groups either have no effect (so the account effectively remains as User only) or cannot be set (e.g. Administrators).

18. Select the "Power Users" group then click **OK**.

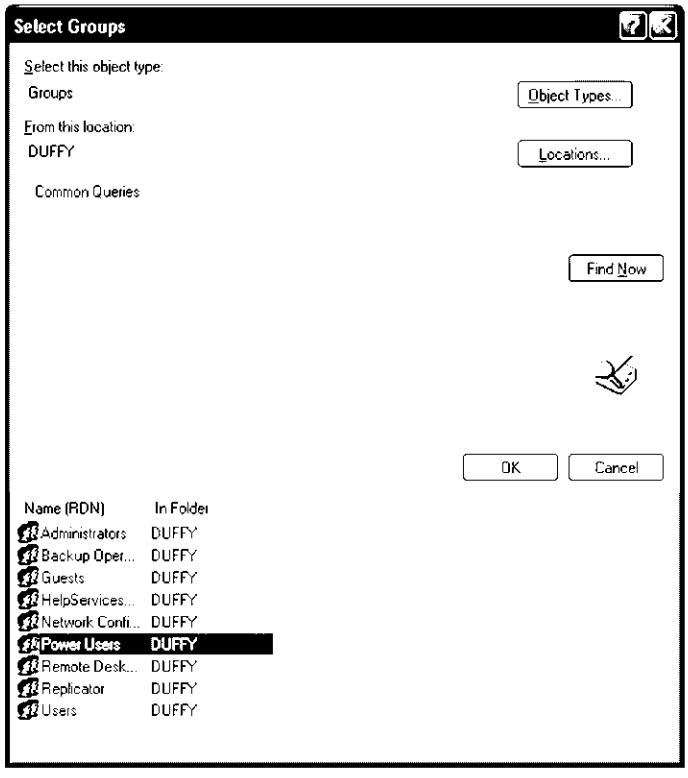


Figure 43: Selecting the Power Users access group

19. From the collapsed "Select Group" window click **OK** to confirm the access level setting.
20. The account properties window will now indicate that the account is now a member of the "Power Users" group.

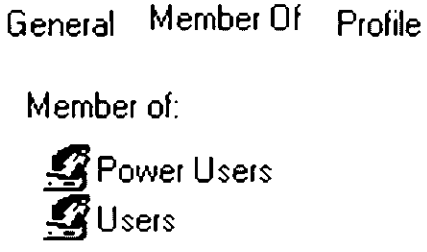


Figure 44: "Power Users" added to user properties

21. Click **OK** to finalize the account setup procedure for this account.
22. To alter the access level for other accounts repeat steps 12 to 21.
23. When all accounts are finalized, close the "Computer Management" and "Administrative Tools" windows.
24. The new accounts will be available at logon time.

4.2 slide label configuration

Users with supervisor rights can configure their own slide labels with the Bond slide label editor, opened from the Configuration menu, Local submenu. The editor allows selection of the information to include, and placement and sizing of text on labels.

Optionally, label layouts can be saved as files and restored for use as required. The uneditable default layout can always be restored.

LIS-ip users can configure two distinct layouts, one each for Bond and LIS slides. A separate command in the Configuration menu opens the label editor for LIS slides. LIS label configuration is identical to Bond label configuration, and the default layouts for each are the same. See "slide labels" on page 199.

Always include sufficient information on labels to ensure that, in the case that automatic label identification fails, the labels can be identified manually. The Label ID, which includes the unique Slide ID, is required for automatic detection. However, Vision BioSystems recommends that all slides include the following fields for manual slide identification:

- Case ID or Patient name;
- Tissue type — to identify control tissues; and
- Marker — the primary antibody or probe to be applied.

4.2.1 slide label editor overview

The major components of the Bond slide label editor are shown in Figure 45:

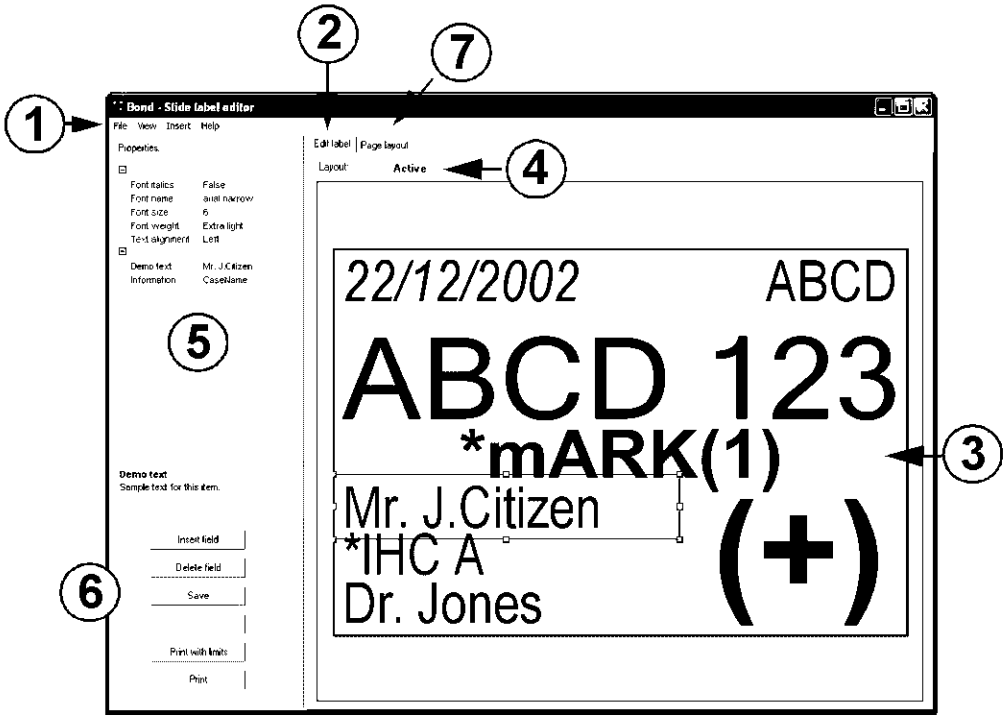


Figure 45: The Bond slide label editor

The editor includes:

- Menu bar (item 1) with all commands available in the editor.
- Edit label tab (item 2) which displays the layout currently loaded in the editor (item 3).
  - The layout consists of information fields configured to report various slide properties. The fields use sample text for the display in the editor. When a field is selected its boundaries are displayed. You can view the boundaries of all fields at once with "Show field limits" in the View menu.
- The Layout field (item 4) at the top of the Edit label tab reports whether the displayed layout is active (i.e. will be used for printing) or an inactive saved file, in which case the file name is shown (see "usage overview" below for further explanation).
- Properties panel (item 5) with configuration settings for the item selected in the layout on the Edit label tab.
- Command buttons (item 6), for commonly used commands.
- Page layout tab (item 7), for label positioning settings for the printer.

The Page layout tab is set up by the Vision BioSystems™ representative during installation and under normal conditions should not require any changes. For this reason the functionality of the tab is not documented here. Please contact your Vision BioSystems representative if you are having problems with text printing off labels.

usage overview

The label editor always opens with the current active layout displayed. The active layout is the one used for any labels that are printed. This status is indicated with "Active" reported in the Layout field above the layout display.

You can edit the active layout, but must then save your changes (by pressing **Save**) to have the new layout used.

Layouts can be saved as files for future use with Save as (File menu). Saved files are loaded into the editor with Open (File menu).

If a saved file is opened into the editor the file name is reported in the Layout field. The layout **is not active**. It can be edited and the edits saved, but the layout will not be used for printing until it is made active. To make it active you must press **Use this layout**. You must save any changes made to a layout file before you can make it active.

Edits to saved layouts can only be made while the layout file is open and inactive, i.e. if you open a saved layout and then make it active, edits you then carry out to the active layout will not change the saved file, only the active layout.

The system default layout can always be restored, to both the active layout and to saved layout files, with "Restore default layout" in the File menu. The default layout itself is uneditable.

4.2.2 setting a new label layout

The label editor always opens with the active layout displayed. To set a new label layout, either edit the active layout directly, or open a saved layout. Instructions for both options are given below.

edit the active layout

1. Edit the active layout as normal (see "editing labels" below).

   If you wish, revert to the default layout with "Restore default layout". Further edits can be based on this.

   To check how the layout will look on labels, use the Print options while editing.
2. When satisfied with the layout, press **Save**.

   The new layout is now active and will be used for any new labels.
3. Exit the label editor.

use a saved layout

1. Open a saved layout file into the editor with "Open" in the File menu.
2. If you are happy with the layout, press **Use this layout**.

   The layout is made active, and will be used for any new labels. You can exit the label editor.
3. If you want to change the layout in the saved file, edit as normal (see "editing labels" below).

   If you wish, revert to the default layout with "Restore default layout". Further edits can be based on this.

   To check how the layout will look on labels, use the Print options while editing.
4. When satisfied with the layout, press **Save**.

   This saves the new layout in the file, but the layout remains inactive.
5. Press **Use this layout**.

   The new layout is now active and will be used for any new labels.
6. Exit the label editor.

4.2.3 editing labels

Label layouts are created by positioning the information fields within the label space, selecting the information to be reported in these, and formatting them. When you select the information field that you want to edit — by clicking on it in the Edit label tab layout display — it populates the fields in the Properties pane to the left with the settings for that field. These settings can then be changed.

You must always start editing from an existing layout, be this the current active layout or a saved layout that you have opened into the editor.

Specific editing options are listed below.

- To change the position of an information field, click on the field then drag it to the desired position.
  You can use the keyboard arrow keys to make small adjustments to the field position.

  You can safely overlap fields in order to position the text closely on the labels, but ensure that the text itself does not overlap.

- To change the width of an information field, click on the field and then drag the white sizing handle at either end.
  Use the keyboard arrow keys with Shift to make small adjustments.

  Information field height cannot be independently adjusted; this is automatically determined by the font settings for the field.

  Try to set field widths that will be adequate for the information that is to be displayed, e.g. case numbers might be of a known length, but patient and doctor names will vary and can be long. If the information to be displayed on a particular slide is too long for the field the information is truncated and ellipsis points appended so that it is clear that truncation has occurred.

- To change the information reported in an information field (refer to "information types" on page 73 for a complete listing of information types):
  (i) select the field
  (ii) open the General section of the Properties table in the left-hand panel
  (iii) select "Information" to display a dropdown menu arrow in the neighboring field
  (iv) open the dropdown menu and select the new information type.

  See "information types" on page 73 for a list of all available information types.

- To change the font characteristics of the text in an information field:
  (i) select the field
  (ii) open the Font section of the Properties table in the left-hand panel
  (iii) select the font property that you want to change.

  For most font properties select settings from the dropdown menu in the neighboring field, but for font size you must type the value directly into the field.

  Editable font properties are:
  - italics: on or off
  - font: a large range of fonts are available, but note that not all of these may be available to the printer, which will use a default font in case an unavailable font is selected
  - font size: allows values from 1 up — the printer uses the nearest font size available
  - font weight: several font weights available — the printer uses the nearest weight available

- To change text alignment within its information field:

(i) select the field
(ii) open the Font section of the Properties table
(iii) select Text alignment
(iv) select right, left, or center alignment from the dropdown menu.

- To add a new information field to the label, press **Insert field**.

  A new field is added in the top right-hand corner of the label. Click on the text "New item" to select the field and follow directions above to position it and set the information type and font properties.

- To remove an information field click on the relevant text to select the field and then press **Delete field**.
  The keyboard Delete key can also be used.

  Note that deleting the sample text in an information field, in the "Demo text" field in the Properties pane, only removes it from view in the editor. The information will still be printed when labels are actually created.

- To change the sample text used for an information field in the editor:
  (i) select the field
  (ii) open the General section of the Properties table
  (iii) select Demo text
  (iv) type the new sample text into neighboring field.

  Note that this changes the text you see in the editor for a particular information type — it makes no difference to the values that will actually print on labels.

4.2.4 default layout

The Bond system is supplied with a default label layout, set during installation. The default layout cannot be changed.

The default layout can be restored at any time, to the active layout or to a saved file that is open in the editor. Select "Restore default layout" in the File menu to do this.

The default layout has the information fields shown below:

- Label ID: includes the slide ID (4 characters) and 3 additional characters used by the system to confirm slide ID. This field cannot be edited as it is used by Bond to identify the slide.
- Slide date: the date the label is printed.
- Slide ID: as set in the Bond software.
- Marker: the name of the antibody or probe to be used on the slide.
- Patient name: the name of the patient.
- Staining protocol name: the abbreviated name of the staining protocol.
- Doctor name: the referring doctor's name.
- Tissue type: marks negative and positive control tissue with "(–)" and "(+)" respectively. Nothing is printed in the field for test tissue.

4.2.5 saved layouts

Multiple layouts can be created and saved as *.ini files. These can then be opened in the label editor to restore the saved configuration.

To create the first layout configuration file, open the default layout, edit it, and then use Save as. Continue to use Save as to create additional files.

Files that you create can be edited and resaved with the changes.

Use Open in the File menu to load your saved layout files into the editor.

Be sure to press **Use this layout** after opening a saved layout file if you want to use it, otherwise the previous label layout will continue to be used, even though the new layout is displayed in the editor.

4.2.6 printing layouts

You can check to see how labels will look by printing a sample directly from the label editor. The label on display in the editor, with sample text, is used.

Optionally, use **Print with limits**, which includes the field boundaries for each information type on the label. This option is only available from the editor — labels printed from Bond never show these boundaries.

It is acceptable that field boundaries overlap each other. This will not affect labels unless the text within the fields actually overlaps, in which case the text is superimposed.

4.2.7 information types

Label information fields can be configured to show any of the following slide information.

Field	Description
Case ID	The case ID for the slide (N.B. not the Case No.)
Doctor comment	A comment recorded in the Bond system for the referring doctor (see "editing a doctor" on page 76)
Doctor name	The name of the referring doctor
Patient name	The patient name
Slide comment	Slide comment (see "creating a slide" on page 126)
Slide date	The date that the label was printed (short format)
EIER protocol name	Abbreviated name of the enzyme protocol
HIER protocol name	Abbreviated name of the HIER protocol
Hybridization protocol name	Abbreviated name of the ISH hybridization protocol
Label ID	The label ID, consisting of the four slide ID characters plus a further 3 characters added for checking slide identity
LIS reference [2–8]	LIS slide properties imported into Bond. See "LIS slide properties" on page 194
Marker	Abbreviated name of the primary antibody or probe
Pretreatment protocol name	Abbreviated name of the pretreatment protocol
Public name	For LIS-ip systems, the public name of the primary antibody or probe (see "public marker names" on page 193)
LIS doctor comment	For LIS-ip systems, the comment for the doctor in the LIS system
LIS doctor name	For LIS-ip systems, the doctor name
Slide priority	For LIS-ip systems, the priority rating for the slide
Staining protocol name	Abbreviated name of the staining protocol
Dispense volume	100 µL or 150 µL dispense volume
Tissue type	Test tissue, or positive or negative control tissue. Bond prints "(–)" for negative control, "(+)" for positive control, and nothing for test tissue.
Slide ID	4-character alphanumerical slide ID, unique to the slide within the Bond system. This is the first part of the label ID.
Facility name	The name of your laboratory, as entered in the Site preferences dialog (see "site preferences" on page 78)

4.3 ID scanner port settings

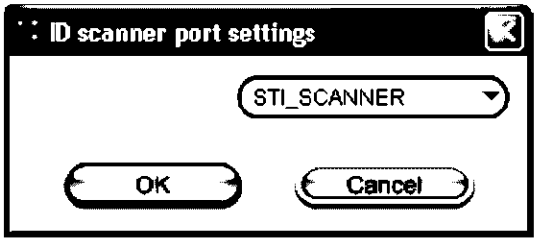


Figure 46: ID scanner port settings

The handheld ID scanner may connect to either a serial or USB port on the host computer. If the ID scanner is replaced the ID scanner port setting may need to be altered. This will normally be done by your service organization but you may adjust these settings if required.

To set the ID scanner port, first select "ID scanner port settings" from the *Local* configuration menu then select the appropriate option from the *Port:* drop-down list. Click **OK** to confirm the setting or **Cancel** to exit without making any changes.

4.4 sound setup

The Sound setup dialog allows you to configure the audible alerts that sound during certain Bond events. Select "Sound setup..." from the *Local* configuration menu to open the Sound setup dialog.

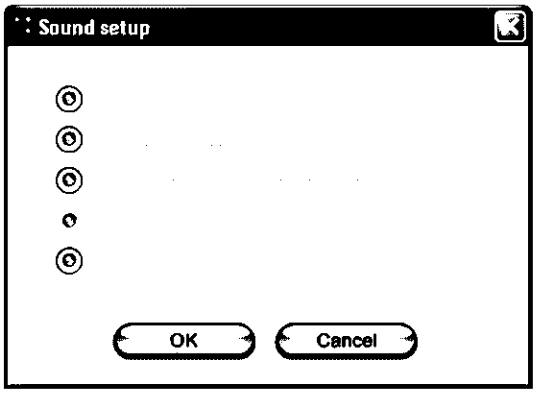


Figure 47: Sound setup dialog

You may select each of the following options to play when an event occurs:

- Play welcome — plays the welcome message when the Bond software launches
- Play new message notification — plays a tone to indicate that an event is has occurred; the tone indicates the alert severity (notification, warning or alarm)
- Play Processing Module identification — plays a voice message identifying the Processing Module (that is it reads out the Processing Module name)
  This message is not available for all languages
- Play event description — plays a voice message that describes the event
  This message is not available for all languages
- Play end of message notification — plays a tone to indicate that the message has ended; the tone indicates the event severity (information, warning or alarm).

4.5 doctors list

The Doctors list allows you to view and modify the list of doctors registered on the Bond system. Select "Doctors list..." from the *System* configuration menu to open the Doctors list dialog.

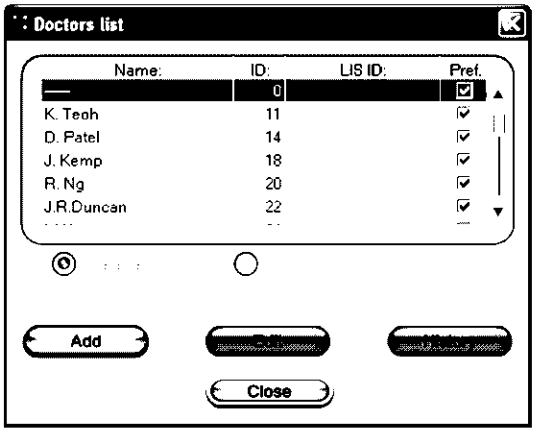


Figure 48: Doctors list dialog

The Doctors list dialog displays a list of doctors registered in the Bond system. The list can be configured to show only preferred doctors (select the Preferred radio button) or all doctors (select the All radio button). The following fields are displayed for each doctor:

- Name: — the doctor's name
- ID: — a unique ID automatically generated and assigned by the Bond system
- LIS ID: — a unique identifier supplied by a Laboratory Information System (refer to Chapter 11 "LIS integration package")
- Pref. — doctor's preferred status (only preferred doctors are available in the drop-down list when creating cases). This status is set in the Edit Doctors dialog.

These values are also shown in the Edit Doctors dialog, where the name can be edited. In addition, the Edit Doctors dialog has:

- Comments: — editable field for a general comment or additional name information.

4.5.1 adding a doctor

Use the following instructions to add a doctor to the list.

1. Click **Add** from the Doctors list to open the Edit Doctors dialog.

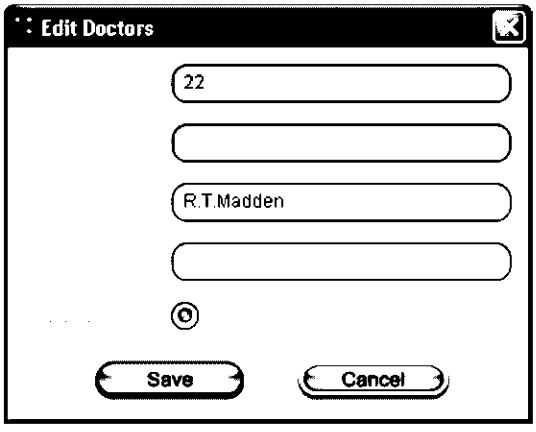


Figure 49: Edit doctors dialog

2. The ID: field is automatically set to the next available unique ID number.
   The LIS ID: field is reserved for LIS use and is not editable.
3. Enter the doctor's name into the Name: field.
4. Enter a comment into the Comments: field if required.
5. Set the Preferred option (blue center sets "Preferred" as shown in Figure 49)
6. Click **Save** to add the new doctor to the list.
   Clicking **Cancel** closes the dialog without adding the doctor to the list.

4.5.2 editing a doctor

Use the following instructions to edit a doctor's details.
Note that the Bond system tracks doctors by the unique Doctor ID number.
Do not use the Edit facility to change the identity of an existing doctor.

1. Select the doctor from the Doctors list dialog.
   Click anywhere on the doctor's row; the selected doctor is highlighted blue.
2. Make the required changes in the Edit Doctors dialog. The following fields are editable:
   (i) Name:
   (ii) Comments:
   (iii) Preferred
3. Click **Save** to confirm the changes.
   Clicking **Cancel** closes the dialog without saving the changes.
4. Any changes (excluding a change to preferred status) will be reflected in the Doctor's history dialog.

4.5.3 doctor's history

The Doctor's history dialog details the changes made to each doctor's details.

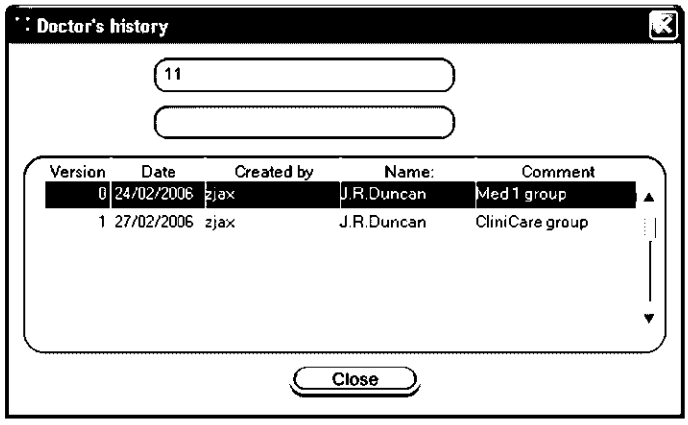


Figure 50: Doctor's history dialog

The Doctor's history dialog includes the following fields:

- ID: — the unique identifier for each doctor
- LIS ID: — a unique identifier supplied by a Laboratory Information System
- Version — the version increments each time a doctor's details are altered
- Date — the date of initial creation (version 0) or change (subsequent versions)
- Created by — the logon name of the person who made the changes
- Name — the doctor's name
- Comment — any comment associated with the doctor.

4.6 site preferences

The Site preferences dialog allows you to set the facility name as well as the default preparation protocol and the dispense volume mode for new cases. Select "Site preferences..." from the *System* configuration submenu to open the Site preferences dialog.

To save any altered settings, click the **OK** button. To exit without saving any changed settings, click the **Cancel** button.

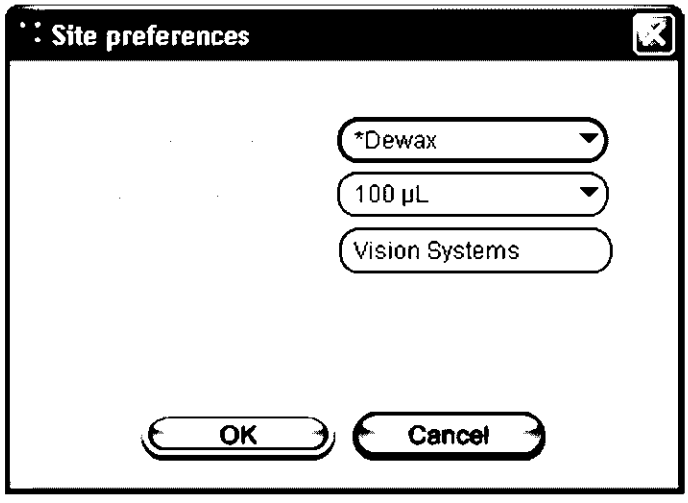


Figure 51: Site preferences dialog

Use the instructions in the following points to set the site preferences.

Bond-max

- To set a default preparation protocol, select the preferred option from the *Default preparation* drop-down.

  You can alter the pretreatment setting for individual cases or slides.
- The *Default dispense volume* sets the dispense volume that is selected by default when you add a new case at the slide setup screen.

  You can change the dispense volume for individual cases or slides either by changing the setting while setting up cases or slides at the Slide setup screen or by changing the properties of existing cases or slides before any of the slides have been processed.

  Note that all slides using ISH staining require 150 µL dispense volume.
- The *Facility name* appears in each report. You can enter up to 16 characters of text in this field to appear in your reports.

The site preferences options also appear in the options table (refer to "processing module configuration" on page 80). However, it is far simpler and faster to use the Site preferences dialog so we recommend that you do not alter the values in the options table. The option values are shown in the following table for reference only.

Section	Key	Default value
CaseSetup	DefaultDewaxProtocolId	9100
CaseSetup	DefaultTissueSize	1
General	Labname	

Note that the Labname key only appears after an initial facility name has been entered using the Site preferences dialog.

4.7 report printer configuration

After generating a report, you can configure the printer and print options using the Print dialog. To open the dialog, click the printer configuration icon in the report window toolbar.

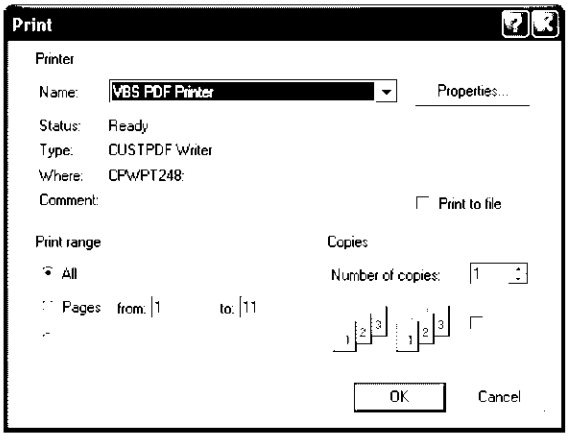


Figure 52: Print configuration dialog

From the Print dialog you can set the number of copies to print as well as the page range. You also have the option of collating copies on the printer.

To choose a different printer, simply select it from the *Name*: drop-down list. This list will display all installed printers. If you wish to alter printer properties, click the Properties button. The printer properties available will depend on the printer selected. You should consult the documentation accompanying your report printer for more details.

printing to a file

If you wish to print to a file rather than to a printer, select the "VBS PDF Printer" from the Print Setup dialog. This printer will produce a file in "PDF" format that can be stored and sent electronically.

4.8 processing module configuration

To avoid the risk of compromised staining, or damaged tissue you should not alter any Processing Module configuration settings whilst any batches are running or any slide trays locked.

The Processing Module configuration functions allow you to deactivate Processing Modules and change critical Processing Module properties. Incorrect use of these functions may leave a Processing Module unavailable for use. You should only attempt to alter the Processing Module configuration under instruction from your service organization, Vision BioSystems or if you have a thorough understanding of the changes you intend to make.

Select "Processing Module configuration..." from the *System* configuration submenu to view and edit Processing Module configuration.

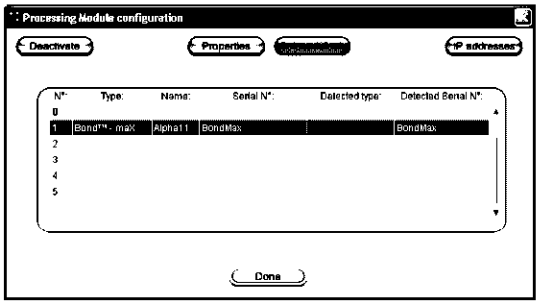


Figure 53: Processing Module configuration dialog

Each row in the Processing Module configuration dialog (see above) represents a Bond instrument as displayed on the Processing Module tabs. This includes those not currently active.

4.8.1 processing module name

Use the following procedure to change a Processing Module's name:

1. Select the Processing Module in the list, then click **Properties**.
   The software displays the "PM Properties" dialog.
2. To change the name, enter the name in the *Name:* field.

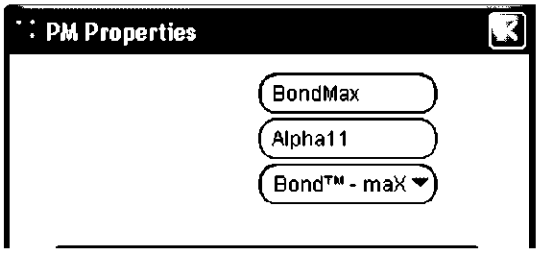


Figure 54: Detail of PM properties dialog with editable Name: field

3. Click **OK** to set the requested changes or click Cancel to exit and retain the initial values.

4.8.2 bulk reagent container configuration

Bond-max For Bond-max you may disable the Dewax, ER1 and ER2 bulk reagent containers. This is useful if you do not use the containers as once they are disabled you may remove the containers from the instrument. This will speed up the instrument initialization and also means that you will not need to maintain fluid in the disabled containers.

Use the following procedure to change the bulk reagent container configuration for a Bond-max instrument.

1. Select the Processing Module in the list, then click **Properties**.
   The software displays the PM Properties dialog.
2. Click the ▼ symbol in the field associated with the container you wish to change (see Figure 55).

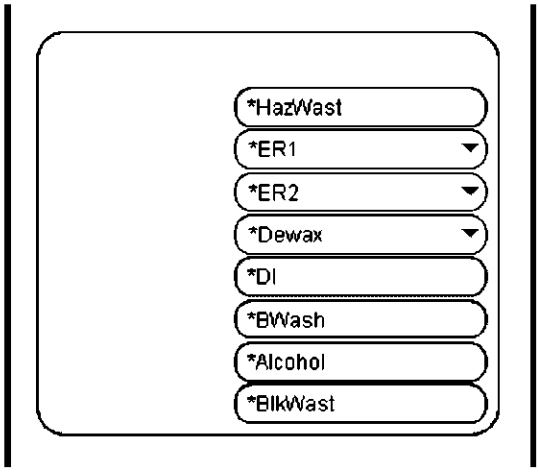


Figure 55: Detail of Bond - Max properties dialog showing containers 2, 3 and 4 as configurable

3. From the drop-down list select either no container or the standard Bond container for the particular location.

Figure 56: Container configuration options with standard container option highlighted

4. When you have configured each container, click **OK** to set the requested changes or click Cancel to exit and retain the initial values.
5. You must shut down and restart the host computer and the affected Processing Module for any changes to take effect.
6. Disabled containers will no longer be displayed on the status screen and they may be safely removed from the instrument.

4.8.3 deactivating a processing module

To deactivate a Processing Module, select it from the list in the Processing Module configuration dialog then click **Deactivate**. Once deactivated, the system no longer attempts to connect to the Processing Module and the Processing Module remains unavailable until it is reinstalled.

4.8.4 processing module IP address

Each instrument has an IP address that identifies it to the network. You cannot alter this address but you can view the address of each instrument by clicking **IP addresses** in the Processing Module configuration dialog. This information may be of use to your service organization.

4.9 options table

The Options table (Configuration menu / System / Option settings) allows you to view or modify settings that control a range of customizable Bond functions.

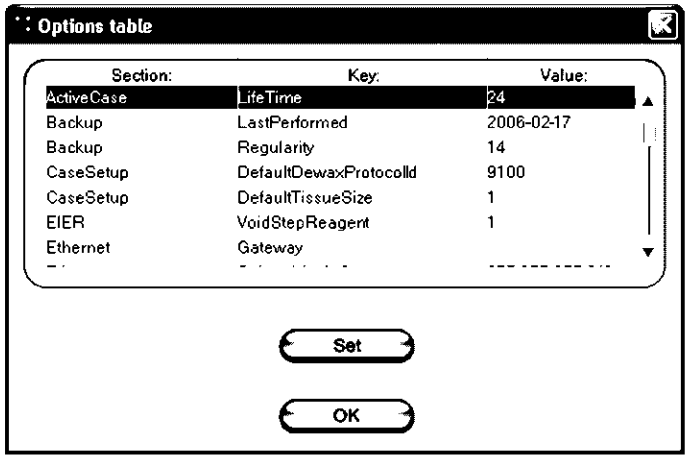


Figure 57: The Options table

Each option in the table has a row with three columns. The columns represent:

- Section: — groups the options with related functions
- Key: — is the unique name for each option
- Value: — sets the option.

4.9.1 options list

The following table lists all of the available options. You should not attempt to adjust any option unless you fully understand the consequences — these settings can have a considerable effect on Bond operation. Each option is detailed in the user manual section most closely associated with the key's function (items with grey background are view only).

Section	Key	Value (Default)	Refer to
ActiveCase	LifeTime	0	"case expiry" on page 123
Backup	LastPerformed	(last date)	"the bond database" on page 60
Backup	Regularity	14	"the bond database" on page 60
CaseSetup	DefaultDewaxProtocolId	9100	"site preferences" on page 78
CaseSetup	DefaultTissueSize	1	"site preferences" on page 78
DataUpgradeHistory	13	(last date)	Shows the date of the most recent database update
Ethernet	Gateway		"computer" on page 38
Ethernet	SubnetMask_0	255.255.255.240	"computer" on page 38
General	DataVersion	13	"software updates" on page 61
General	LabName		"site preferences" on page 78
General	PABReplacement	2	"negative reagent control for IHC" on page 231
General	ShowSlideTempAbove	35	"temperature indication" on page 102
IdentificationOptions	CreateDailyCase	CreateDailyCaseOff	"daily case option" on page 135
IdentificationOptions	CreateOnFly	CreateOnFlyNothing	"impromptu slide and case creation" on page 132
IdentificationOptions	ForceLISPrinting	ForceLISPrintingOn	"external slide labels" on page 200
IdentificationOptions	ForceNativePrinting	ForceNativePrintingOn	"external slide labels" on page 136
IdentificationOptions	ShowResurrected	ShowResurrectedOff	"setting new case and new slide options" on page 134
Install	DBSystemVersion	0005	Reports the database version installed
LISReferences	LISRef2Name		"LIS slide properties" on page 194
LISReferences	LISRef2Visible	1	"LIS slide properties" on page 194
LISReferences	LISRef3Name		"LIS slide properties" on page 194
LISReferences	LISRef3Visible	1	"LIS slide properties" on page 194
LISReferences	LISRef4Name		"LIS slide properties" on page 194
LISReferences	LISRef4Visible	1	"LIS slide properties" on page 194
LISReferences	LISRef5Name		"LIS slide properties" on page 194
LISReferences	LISRef5Visible	1	"LIS slide properties" on page 194
LISReferences	LISRef6Name		"LIS slide properties" on page 194
LISReferences	LISRef6Visible	1	"LIS slide properties" on page 194
LISReferences	LISRef7Name		"LIS slide properties" on page 194
LISReferences	LISRef7Visible	1	"LIS slide properties" on page 194
LISReferences	LISRef8Name		"LIS slide properties" on page 194
LISReferences	LISRef8Visible	1	"LIS slide properties" on page 194
Options	LIS interface		"LIS connection and initialization" on page 195
ProtocolRules	acceptableBatchStartTimeLimit	900	"batch progress" on page 112
ProtocolRules	acceptableBatchStartTimeLimitAlarm	1500	"batch progress" on page 112
ProtocolRules	acceptableBatchStartTimeLimitDewax	3600	"batch progress" on page 112
ScoreSystem	Score0	-	"scoring slides" on page 177
ScoreSystem	Score1	+	"scoring slides" on page 177

Section	Key	Value (Default)	Refer to
ScoreSystem	Score2		"scoring slides" on page 177
ScoreSystem	Score3		"scoring slides" on page 177
ScoreSystem	Score4		"scoring slides" on page 177
ScoreSystem	Score5		"scoring slides" on page 177
ScoreSystem	Score6		"scoring slides" on page 177
ScoreSystem	Score7		"scoring slides" on page 177
ScoreSystem	Score8		"scoring slides" on page 177
ScoreSystem	Score9		"scoring slides" on page 177
UserName	UseDomain	0	"system logon and access level" on page 47

4.9.2 viewing and editing options

To view an option simply scroll through the options list until you find the key you require.

Use the following instructions to edit an option's value.
Note that some options are not editable and the **Set** button is inactive for these items.

1. Scroll through the options list until you find the row you wish to edit.
2. Click on any part of the row to make it active.
   Active rows are highlighted blue.

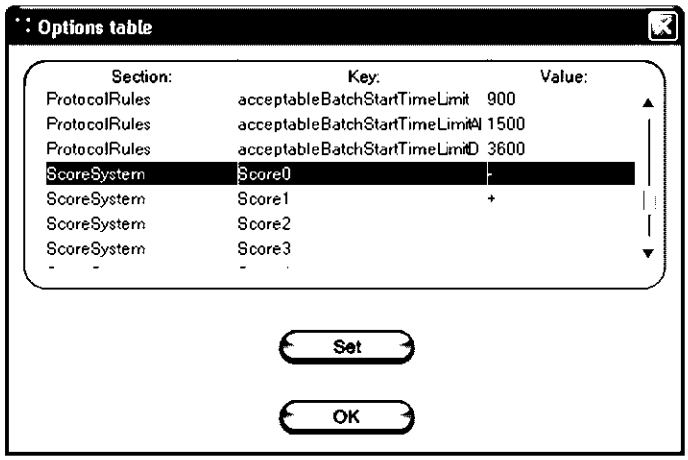


Figure 58: Selecting the row for the "Score0" key

3. Click **Set** to open the "Option details" dialog.

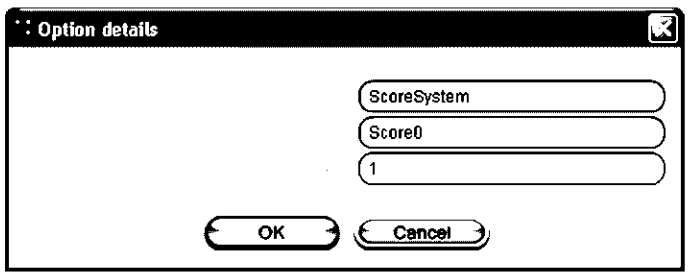


Figure 59: Setting the score value in the options dialog

4. Enter the required value into the *Value:* field.
5. Click **OK** to confirm the new value.
6. You will now return to the "Options table" dialog and the new value will be shown in the corresponding row.
   Click **OK** to return to normal Bond operation.
7. Note that the changes will not become active until the Bond software is closed and restarted.

5

quick start

This chapter is designed to take you on a guided tour of your first individual run with the Bond™ system. We will create some example test cases and run protocols that are installed with your system.

Before you start you should be familiar with the "hardware" and "software overview" chapters of this manual. The procedures in this chapter assume that you are familiar with the basic navigation and editing operations described in Chapter 3 "software overview".

5.1 preliminary checks

Before starting the Bond system, do the following:

1. Check generally for cleanliness, cleaning where necessary.
2. Check the aspirating probe tubing for blockages or bubbles.
   If you see bubbles, prime the system by turning the Processing Module off, then on again.
3. Wipe the aspirating probe with 70% alcohol, being careful not to bend the aspirating probe.
4. Wipe the heater blocks (Bond-max) or wash plate (Bond-x) with 70% alcohol.
   Refer to "slide staining assembly" on page 208 for additional details.
5. Check that the Slide Staining Assembly springs are intact.
   Replace them if necessary. (Refer to "covertile clamps" on page 211 for details.)
6. Make sure the bulk waste and hazardous waste containers are empty.
7. Make sure the slide tray is clean.
8. Check that the bulk reagent containers are full.
9. Check that the slide labeller has an adequate supply of labels. If the roll looks depleted, then ensure that a replacement roll is available.

5.2 start the bond system

If everything is in order, then start the Bond system.

1. If the Processing Module and computer are not on, turn them on now.
2. When the computer is running, start the Bond software.
3. Once the software has started, check the Status screens to ensure there are no Processing Module errors (refer to Chapter 6 "status screens").
   Correct any errors before attempting to run any batches.
4. Power up the Slide Labeller.

5.3 case and test details for quick start

The quick start examples use IHC antibodies and protocols. The procedures described are also valid for ISH probes and protocols (simply swap the antibody for a probe and replace IHC protocols with ISH protocols). Also, the antibody clone used depends on the reagents installed in your Bond software. We have simply used the generic antibody term in the following tables.

We will use the following cases in our example.

Case ID	Patient name	Doctor
3688	Edward, A.	Smith
5693	Bond, H.	Smith
10505	Schmid, N.	Smith

All of the tests will be run using the protocol labelled "*IHC Protocol F".
We will run a selection of antibodies on each case as shown in the following table.

Antibody	3688	5693	10505
CD3		✓	
CD5	✓	✓	
CD10			✓
CD20	✓	✓	✓
CD23			✓
Melan A	✓		
Tyrosinase	✓		

5.4 prerun checks

You should check that the protocols and reagents you are going to use in the run are set up in the software.

You should only need to do these prerun checks when first running any protocol.

To check the protocols:

1. Select the protocols icon (shown at the right) from the function bar.

2. Check that "*IHC Protocol F" is listed in the table.

   If the protocol is not listed, or you want to view or edit the protocol steps, see Chapter 8 "protocols".

3. Select the protocol in the table, click **Open**, and note the preferred detection system in the *Edit protocol properties* dialog; 'Bond Polymer Refine Detection'.

   Make sure that the protocol is selected as 'Preferred' with the radio button at the bottom of the dialog.

To check the reagents:

This check assumes that you have stock of the required antibodies and detection kit, and that these have been registered in the Bond reagent inventory. See "reagent management" on page 155 for more information.

1. Select the reagents icon (shown at the right) from the function bar.

2. On the Setup tab select 'Primary' and 'All' with the *Show* radio buttons at the bottom of the screen.

   Locate each of the antibodies that we need in the list and ensure that it is checked as 'Preferred'. If not, select the antibody and press **Open** to open the *Edit reagent properties* dialog. Click the 'Preferred' radio button at the bottom of the dialog and then **Save**.

3. Now go to the Inventory tab and select "Reagents", "In stock" and "Preferred" with the *Show* radio buttons at the bottom of the screen.

   All the antibodies we need should appear with the volumes available.

   Make sure that there is sufficient volume for each antibody. For example, there are three CD20 slides, so there should be at least 300 µL of antibody available.

4. On the same tab, select "Detn systems" with the *Show* radio button and check that the preferred detection system, "Bond Polymer Refine Detection" is listed in the table, and that there is enough volume.

   In our example there should be at least 1.0 mL (10 slides x 100 µL per slide) available.

For more information on working with reagents, see "reagent management" on page 155.

Ensure that the ambient temperature is between 18–26 °C to meet all staining performance requirements.

5.5 setting up slides

This section describes the process of telling Bond what to process and how to physically place slides into the Processing Module.

The software operations in this section are carried out from the Slide setup screen. To display this screen, click the Slide setup screen icon from the Function bar.

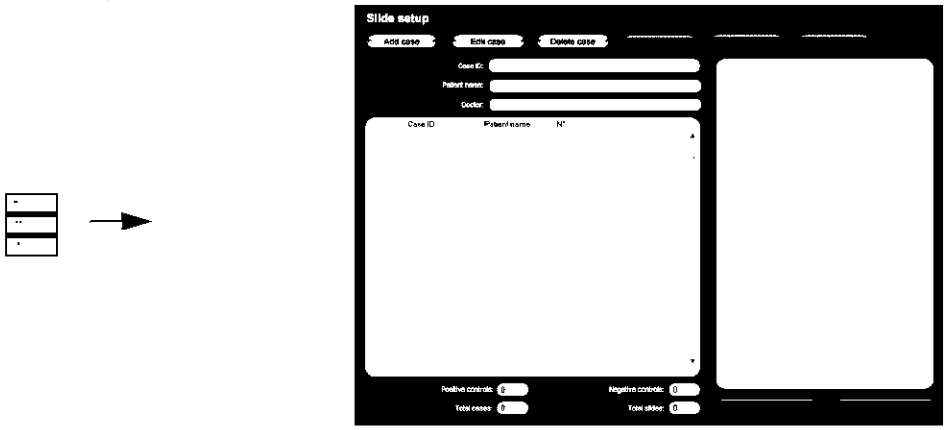


Figure 60: The Slide setup screen

5.5.1 entering case details

Here we will enter the details for the cases given in "case and test details for quick start" on page 87.

1. Click **Add case** at the Slide setup screen. The software displays the *Add case* dialog.

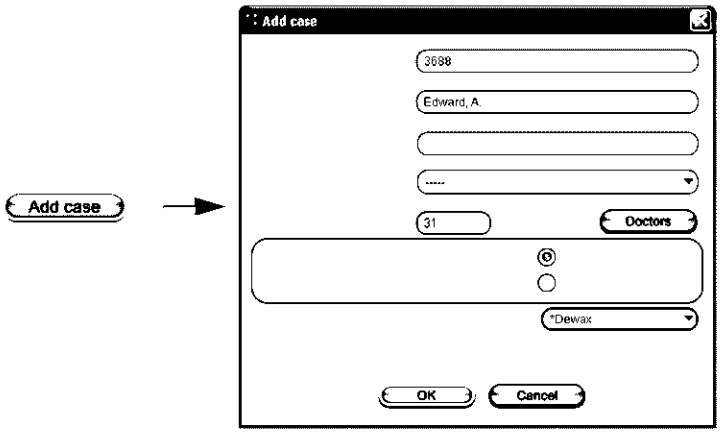


Figure 61: The Add case dialog
(Preparation option only applicable for Bond-max)

2. Click in the *Case ID:* field and type ""3688"".
3. Click in the *Patient name:* field and type "Edward, A.".
4. Click the **Doctors** button to open the *Doctors list* dialog. There, click the **Add** button to open the *Edit Doctors* dialog and type "Smith" in the *Name* field.

   Turn on the *Preferred* radio button, then **Save,** and then close the *Doctors list* dialog.

5. Back in the *Add case* dialog, select "Smith" in the *Doctor:* field.
6. Ensure that the 100 µL dispense volume is selected.

When setting up slides for your own cases, select the dispense volume to suit your own circumstances. For more information, see "slides" on page 41.

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7. Click ▼ in the *Preparation* field to select a default preparation for slides in this case. The preparation may be either Dewax or Bake and Dewax.
8. Click **OK**—the table on the left of the screen now displays the case details.

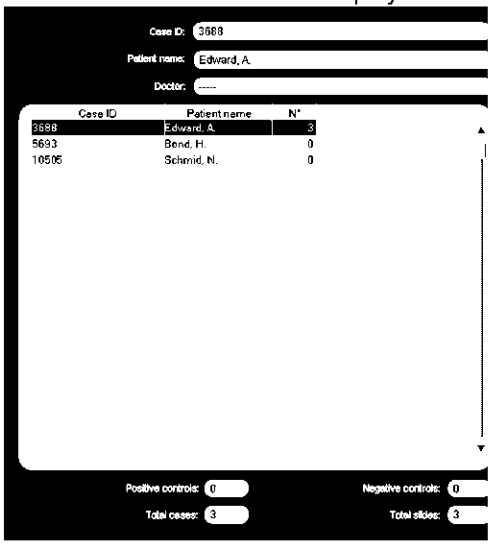


Figure 62: The case list showing the Quick Start cases

You can now enter the other case details or continue to the next section (""entering slide details"") to add the slides for this case.
For more information on working with cases, see "working with cases" on page 121.

5.5.2 entering slide details

To add slides for the case ID 3688, do the following, starting from the Slide setup screen:

1. Click on case ID 3688 in the case list on the left of the screen.
2. Click **Add slide** to display the Add slide dialog.

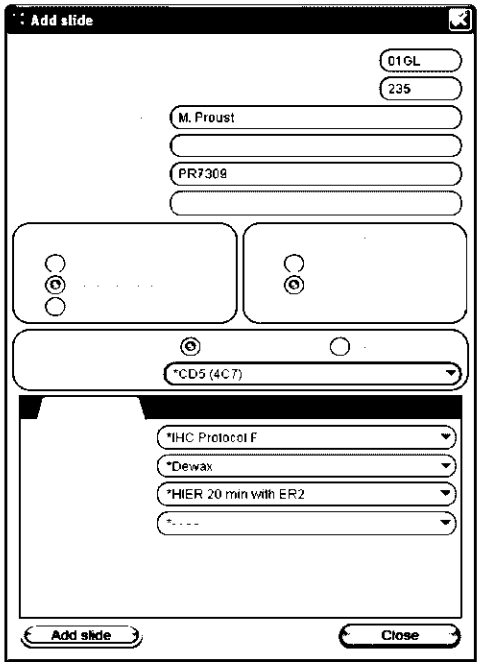


Figure 63: The completed Add slide dialog
(Preparation and retrieval options only applicable for Bond-max)

3. Ensure "Test tissue" is selected as the tissue type.
   If necessary, click the *Test tissue* radio button to select it.
4. Select a dispense volume suitable for the tissue size (see "microscope slides" on page 240).
5. Click the IHC radio button to specify the IHC process.
6. Click ▼ in the *Marker:* field to display a list of primary antibodies.
7. Select ""CD5"" from the list. The software automatically enters the default protocol for this primary in the *Staining protocol:* field.

   For details on changing the default protocol, see "adding or editing a reagent" on page 159.

Bond-max

8. Click ▼ in the *Preparation:* field and select the preparation to be used for this slide.
   The preparation may be either "Dewax" or "Bake and Dewax".

Bond-max

9. To add epitope retrieval steps, click ▼ in either the *HIER protocol:* or *Enzyme protocol:* field to display a list of available protocols and select the one you require.
10. Add a comment if you want, then click **Add slide**.
    The slide is added to the slide list.
    The "Add slide" dialog remains open.
11. Repeat steps 6-10 three times and select ""CD20"", ""Melan A"" and ""Tyrosinase"" as the marker in step 7.

12. After all slides have been added, click **Close** to close the Add slide dialog.

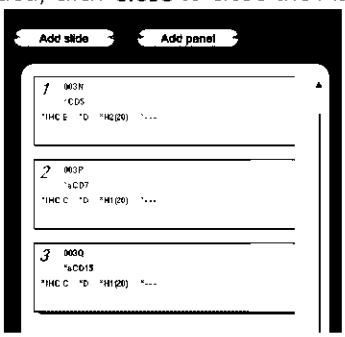


Figure 64: Slide list

13. Review the details in the slide list.
    If you need to change details for a slide, right-click on the slide, select *Slide properties* from the submenu, change the details as required, then click **OK**.

For more information on working with slides, see "working with slides" on page 125.

You can now add the next case as described in "entering case details" on page 89, then follow the procedure in this section to add the slides for that case.

You can also copy case 3688 to create a duplicate case and slides. Refer to "copying a case" on page 124 for detail on how to do this.

Finally add the case details and slides for case ID 10505.
Details for all of slides are now entered into the Bond software.
You should now print slide labels and apply them to the slides.

You can use *panels* to quickly add a number of slides that you commonly use.
For an explanation of panels and how to create and use them, see "reagent panels screen" on page 170.

We strongly recommend that you always run the Bond system with a control tissue on the same slide as the sample tissue. In the unlikely event of a user error (such as accidentally putting a slide ID label on the wrong slide, or forgetting to use a Covertile™) or an instrument error, this procedure will greatly reduce the risk of an incorrectly stained slide going unnoticed.

You can add control slides to control cases by selecting either "Negative tissue" or "Positive tissue" instead of "Test tissue" at step 3 of "entering slide details" on page 91. Set up control reagents by selecting the appropriate reagent from the Marker list during slide setup.

5.5.3 labelling slides

The short date specified in the operating system is printed on the slide label. The Bond software, like most Windows applications, uses the system settings for printing or reporting date and time. In some cases long date and time formats will exceed the space available for the date. To ensure that you do not lose information, set the short date format to a maximum of 12 characters and the long date format to a maximum of 28 characters.

"To ensure the labels print correctly use only the "Bond Universal Slide Label"."

Labels include unique slide identifiers that identify the slides to the Bond system. If the Bond system cannot automatically identify these labels, the slide cannot be processed until the slide is manually identified to the system (see "assisted slide identification" on page 109), or new labels printed and applied to the slides.

Extended soaking in xylene* can reduce the adhesiveness of the slide ID labels. We recommend that slides should not be soaked in xylene* for more than ten minutes.
Slides must be completely dry (wiping with a tissue is not sufficient) before applying the slide ID labels.

If you are using xylene* for dewaxing off the instrument, avoid touching the label so the printing does not become smudged. You can also seal the label with a Bond slide label cover first.

To apply slide labels to the slides:

1. Click **Print labels** from the Slide setup screen.
2. Click "Slides not printed" then click **Print**.

   For more options when printing slide labels, see "slide labelling" on page 129.
3. Ensure the frosted area of the slide (where the label will be applied) is dry, then apply the label with the slide ID aligned with the end of the slide.
   Make sure the label is aligned squarely as the Processing Module cannot properly image misaligned labels.

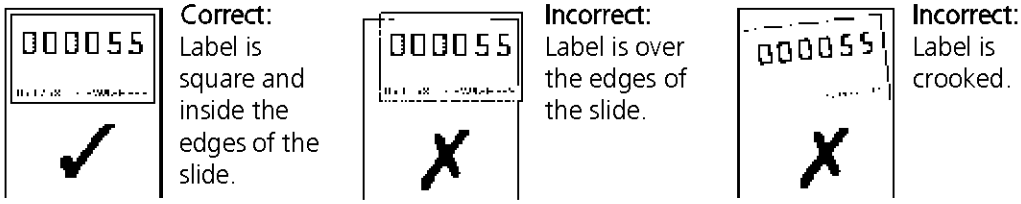


Figure 65: Place the label within the edges of the slide

Caution
Position all parts of the label within all slide edges. An exposed sticky surface may cause the slide label (and slide) to stick to the Covertile or other equipment and damage the slide.

To see the features and controls of your Slide Labeller, refer to the documentation that was supplied with it.
For details on how to load labels and routine maintenance of your Slide Labeller, refer to "slide labeller" on page 219.

* Xylene must not be used on any Bond instrument. If you are using xylene for dewaxing the dewaxing steps must be completed off the instrument.

5.5.4 external dewaxing and epitope retrieval

Dewaxing and epitope retrieval, if this is being done externally to Bond, is best done after labelling the slides. This avoids slides drying out while you enter the details of the slides and set up Bond to run the required protocol(s), and also avoids difficulties in labelling wet slides following these steps.

5.5.5 loading slides

- Before loading your slides, wash or rinse them and allow excess liquid to drain outside the Processing Module, but do not let slides dehydrate.
- All slides on a particular tray must be *compatible*.
- Check that each slide contains an undamaged slide label. If Bond cannot identify the label, or the slide does not carry a label, you will either need to print the label again, or select the slide manually.

Load slides as follows:

1. Hold the slide by the label end with the sample uppermost.
2. Orient the slide over an empty position on the slide tray, with the label end of the slide over the indent of the slide position of the tray (see Figure 66).

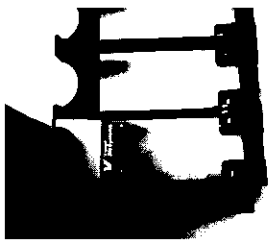


Figure 66: Positioning a slide in a slide tray

3. Rest the other end of the slide in the recesses of the slide position.

Unless dewaxing slides, do not leave uncovered for long periods of time without rehydration with buffer. Allowing tissues to dehydrate leads to poor quality staining.

4. Hold a Covertile by the head, and position it over the slide with the key in the neck aligned with the recess in the tray.

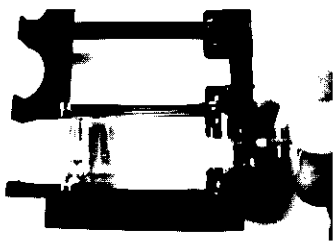


Figure 67: Positioning a Covertile on a slide

Use the Bond Universal Covertile for both Bond-x and Bond-max instruments.

5. Lay the Covertile on the slide, fitting the key into the slot.

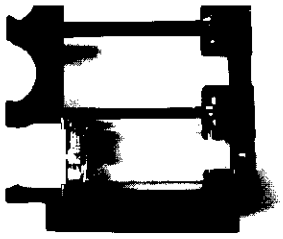


Figure 68: A slide loaded into a slide tray with a Covertile in position

6. When all slides and Covertiles are loaded into the tray, lift the tray and rest the end of the tray at the entrance to an empty Slide Staining Assembly (the handle of the slide tray should be pointing away from the Processing Module).
7. Position the right runner of the tray in the guide of the module entrance, and the left runner flat on the tray.
8. Slide the tray as far as it will go into the module without using force—the tray should slide easily into the module.

5.6 loading the reagents

This section refers to setting up the 7 mL and 30 mL reagents on the reagent platform of the Bond Processing Module, and assumes the reagents are registered for use with the Bond system.

For a complete description of the reagent screens in the Bond software and registering reagents, see Chapter 9 "reagent management".

To load reagents into the Bond Processing Module, do the following:

1. Place the reagent container into a reagent tray by aligning the groove that is contained in one side of the reagent container with the groove in the reagent tray compartment, then press down until the container clicks into place.

Figure 69: Reagent container in reagent tray (The arrows indicate the grooves in the reagent container and in the reagent tray)

2. Open the reagent container by lifting the flip-top lid from the labelled side of the reagent container.

Warning
Be careful when opening reagent containers. It is possible that reagent may collect around the lid during transit and storage, and this may cause droplets of reagent to be flicked out when the reagent container lid is opened. You should always wear approved eye protection, gloves and approved protective clothing when handling reagents and reagent containers.

To open the container, swing the lid back and clip the tab into the clips on the back of the reagent container.

Figure 70: Reagent container with lid clipped back

3. Place the reagent tray on the reagent platform of the Processing Module.
   Use the guides on the platform to guide the tray correctly into the Processing Module.
   When the tray reaches the end of the platform it should engage the interlock.

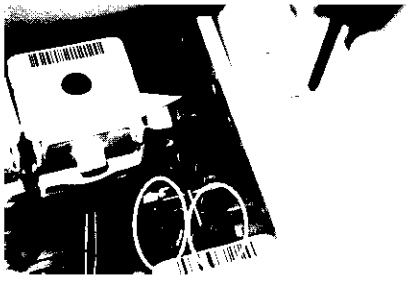


Figure 71: Inserting the reagent tray
(The tray's locking mechanism (left ellipse) engages with the Processing Module's locking port (right ellipse))

The reagent column in the reagent display in the Status screen is displayed in a lighter color with a dark border to indicate that the rack is about to be imaged.

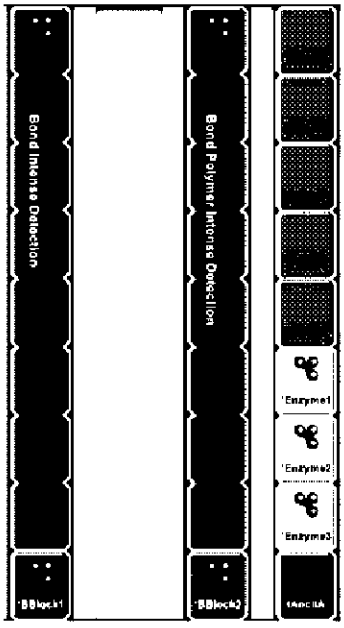


Figure 72: Reagent tray status as shown in the System status screen

4. The Bond system images the IDs on the reagents as soon as the robot is available, then updates the icons for the reagents.

When loading reagents into the Processing Module, click the Processing Module tab to display the Status screen. If there are any problems with reagents, the software displays an attention icon on that screen. Right-click the icon to get more information.

For more information on Status screens, refer to Chapter 6 "status screens".

A reagent tray is locked in position when a reagent on that tray is required within two minutes.

To remove a reagent tray, check that the reagent tray LED is green then pull the reagent tray out of the Processing Module.
If a reagent on the tray is required, the reagent tray LED will be red and the tray will be locked. Do not try to forcibly remove a locked tray as this may damage the instrument.

Note that if processing is already in progress, and reagent in a specific reagent tray will be required within 2 minutes, you can not remove that tray without abandoning the run.
This is indicated by the indicator for that tray glowing red.

For information on fixing reagent problems, see "fixing reagent problems" on page 105.

5.7 running a protocol

The starting point for this section is at least one batch of slides and required reagents loaded into a Bond Processing Module (see "setting up slides" on page 89 and "loading the reagents" on page 95).

Warning
The Bond system uses an aspirating probe and a robotic arm. Either may move without warning, and with a speed that may cause injury.
Do not open the cover while processing is in progress, and do not attempt to by-pass the interlocks.

Ensure that the lid is closed during runs.
The Processing Module will pause runs while the lid is open—if the lid is left open for a long time, slides that are loaded may dry.

Do not shut down the computer during a run. To change the user that is logged on to the computer, use "Log off" from the operating system "Start" menu rather than turning the computer off.

To tell the Bond system to run a protocol on a tray of slides, press the Load/Unload button on the front panel, beneath where the tray is loaded.
Bond locks the tray, and the Slide Tray LED should glow orange.

As soon as the robot is available, the Bond system images the slides. When this happens, you should click the Processing Module tab to display the Status screen. If there are any problems with reagents or slides, the software displays an attention icon on that screen. Right-click on the icon to get more information.
For more information on Status screens, refer to Chapter 6 "status screens".

The Bond system checks that all slides on the tray are compatible, and assigns group letters to the slides if they are not. You must change the slides so they are all compatible before a run can be started. For information on how to fix unrecognized or incompatible slides, see "fixing incompatible slide setup" on page 111.

The Bond system checks that the reagents needed for processing the slides are available.
If any of the required reagents are not available, the software displays an attention icon below the slide list. Right-click on the icon for more information.

Provided there are no unrecognized or incompatible slides, the slides are now ready for a staining run. The progress bar will be in the starting phase (refer to "batch progress" on page 112) and the batch status will be "Slides ready" (refer to "batch status" on page 112).

Click ▶ to begin running the protocol (or you can set the instrument to start later; see "delayed start" on page 116).

The system will schedule the batch then the progress bar will switch to the processing phase (refer to "batch progress" on page 112) and the batch status will be "Proc (OK)" (refer to "batch status" on page 112).

Once a Bond Slide Staining Assembly has begun processing, the Load/Unload button for that Slide Staining Assembly will not release the slide tray. You must click ■ below the tray on the status screen of the Bond software. This abandons the staining process for that tray.

5.8 finishing a run

When the processing run is finished, the Slide Staining Assembly display flashes. (See "processing module tabs" on page 51.) If there were unexpected events during the run, the display text is red and the notification symbol will appear below the batch and on affected slides. If this happens, check the System status screen for attention icons and right-click on them to display information about the attention state. You should also inspect the Run events report (refer to "run events report" on page 178) to see any other information about problems during the run.

When the run has finished:

1. Remove reagent trays.
   Close reagent container lids firmly to prevent reagent evaporation, and immediately store the reagents as recommended on the label or reagent data sheet. Most often this is at 4 °C.
2. If necessary, clean the reagent tray with cool water or 70% alcohol.
3. Press the Load/Unload button and remove slide trays from the Processing Module.

Inspect in and around the Slide Staining Assembly for broken slides in the unexpected event that a misaligned slide is crushed when the slides are locked.
Always exercise care when handling slides to avoid cuts.

4. Remove the Covertiles by holding down the label of the slide, then carefully putting pressure downwards on the neck of the Covertile to lift the end of the Covertile off the slide.

Do not slide the Covertile across the surface of the slide, as you may damage the tissue, making slide reading difficult.

5. Lift the Covertiles from the slides and clean them as described in "covertiles" on page 211.
6. Remove the slides and proceed with the next step in processing them according to your laboratory processes.
7. If you wish to document the quality of processed slides, you can score them using the slide properties functions in the Slide history screen (see "slide properties, slide rerun and scoring" on page 175).
8. You can choose to rerun any slides (see "slide properties, slide rerun and scoring" on page 175).
9. Clean the slide tray in 70% alcohol.
   Do not use hot water or strong detergents as they may cause permanent damage to the tray.
10. Check the Slide Staining Assembly clamps according to "covertile clamps" on page 211.

Schedule a time each day for the daily cleaning and maintenance tasks (see "cleaning and maintenance schedule" on page 205). You should close the Bond software and power cycle (turn off, wait 30 seconds, turn back on) the Processing Module at least once per day; do this when no batches are running.

6

status screens

Each Processing Module has two status screens, selected from tabs at the top right of the window when a module has been selected from the left-hand tabs. The System status screen offers system control from a view that shows slide and reagent placement in the module. The Protocol status screen gives information on protocol progress for individual slides.

6.1 system status screen

This screen allows you to control processing, and it displays the details of slide trays and reagents loaded, as well as displaying status of reagents, waste, and interlocks in the system.

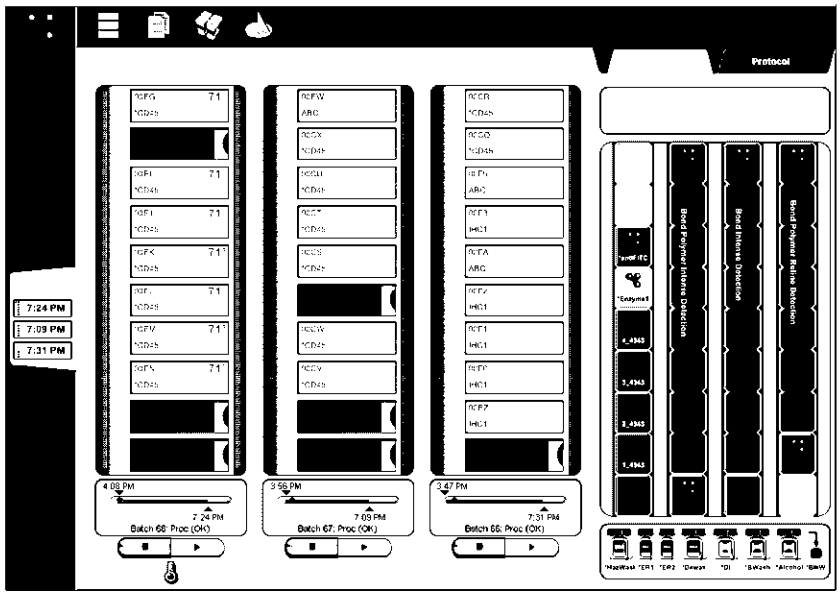


Figure 73: The System status screen

The Processing Module tabs at the left of the status screens give a visual summary of the status of the associated Processing Module. For more information about these tabs, see "processing module tabs" on page 51. Click on the tab to see the detailed status of the Processing Module.

6.1.1 hardware status

The icons at the upper right of the screen display an alert indicator if there is a problem with some part of the Bond system.
Right-click on the indicator to get more information.

General fault with the system.

Either the lid is open or the bulk container cavity door is open.
These must be closed to operate the Processing Module.

Reagent is missing.
Right-click on the icon to get more information.

This alert means the mixing station is missing or expired.
Right-click on the icon to get more information.

If the mixing station is missing you must insert a mixing station and restart the Processing Module in order for the new mixing station to be recognized.

This alert means the mixing station is dirty or not empty.
Right-click on the icon to get more information.

Empty and/or clean the mixing station before continuing.

If there are no clean positions following a series of batches being run, allow time for the Processing Module to clean the mixing stations.

6.1.2 heater errors

Bond-max Each of the Bond™-max slide heaters is independently monitored and will be marked as faulty if a temperature error occurs (see Figure 74). Contact you service organization if a faulty heater is indicated.

Figure 74: Individual heater error

You should not attempt to run a slide that requires heating at a position marked as faulty. If a heater malfunctions during a run you will either compromise the slide at that position or, if the heater malfunction is a safety risk, cause the Processing Module to shut down all slide heating and thus compromise any temperature controlled slide currently processing.

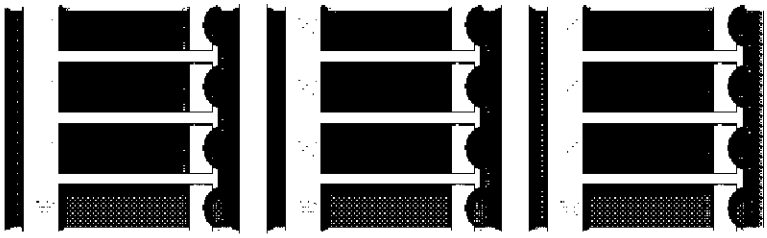


Figure 75: Grey heater symbols at each position indicate a complete heating shutdown

Once slide heating is shut down, you must turn off then restart the Processing Module to clear the heater lock. Be sure that you do not use the faulty heater position until it has been repaired.

You can continue to use slide positions with faulty heaters so long as the slides processed there do not require heating.

6.1.3 temperature indication

Bond-max When a Bond-max Slide Staining Assembly is above ambient temperature, temperature indicators appear near the bottom of the system status screen and the side borders of the slide display. The temperature indicators at the bottom of the screen show that a Slide Staining Assembly is either warm (see Figure 76) or hot (see Figure 77).

Figure 76: Temperature indicator — warm

Figure 77: Temperature indicator — hot

The temperature indicators at the side borders of the slide display are blue when the tray is at ambient temperature, orange when it is warm and red when it is hot.

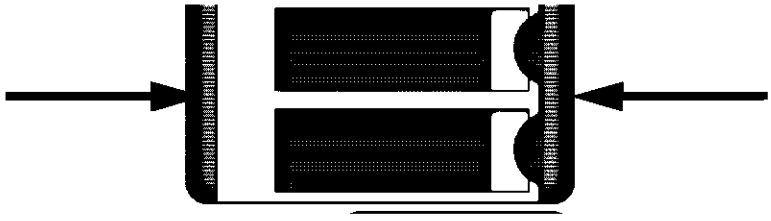


Figure 78: Temperature indication bars

Warning
The Slide Staining Assemblies, and therefore their surrounds and the slides in the Slide Staining Assemblies may be hot enough to cause severe burns if touched.
Do not touch a Slide Staining Assembly until the software indicates that the temperature is cool. If the software is not running, allow at least twenty minutes after power has been disconnected from the Processing Module.

The temperature at which a temperature indicator first appears is configurable and can be altered from the options table (refer to "options table" on page 82). The option details are shown below.

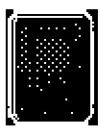
Section	Key	Value	Default
General	ShowSlideTempAbove	Temperature threshold (°C)	35

6.1.4 reagent status

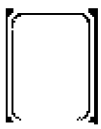
The right side of the status screen displays the status of reagents detected. The icons are explained in the following tables.

An optimized Bond reagent supplied for use with the Bond system. Details for these reagents are automatically entered by the Bond software when you register them. The abbreviated name of the reagent is shown.

Detection System (rotated)



Reagent that is not supplied for use with the Bond system.
These are "open" reagents, which can be supplied by suppliers other than Vision BioSystems™. You must enter the details into the system for these reagents and place them in a Bond open reagent container before you can register them.



The software did not detect a reagent in this position.
If there is a reagent present, see "fixing undetected reagents" on page 105 for details on how to fix the problem. If the imager frequently fails to properly image IDs, clean the ID imager window with a cotton wool bud or a lint-free cloth moistened with distilled water.

Bond detected a problem with this reagent. Right-click the notification symbol for further information.
It may be that Bond did not recognize the reagent. In that case use the hand-held scanner to scan the reagent and add it to the inventory. If the ID is damaged, enter the ID manually. Refer to "registering reagents and detection systems" on page 163 for more information.

Bond detected a problem with one or more components of this detection system. Right-click the information symbol for further information.

Reagent and detection system level is represented by the level of color:

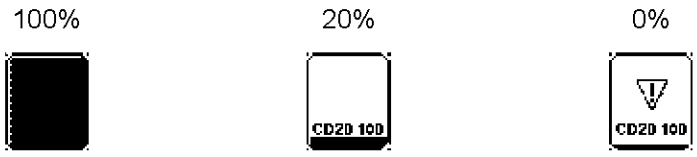


Figure 79: Reagent fill levels

You can also check inventory (see Figure 80) and properties (see Figure 81) for a reagent by right-clicking on a reagent or detection system icon and selecting from the submenu.

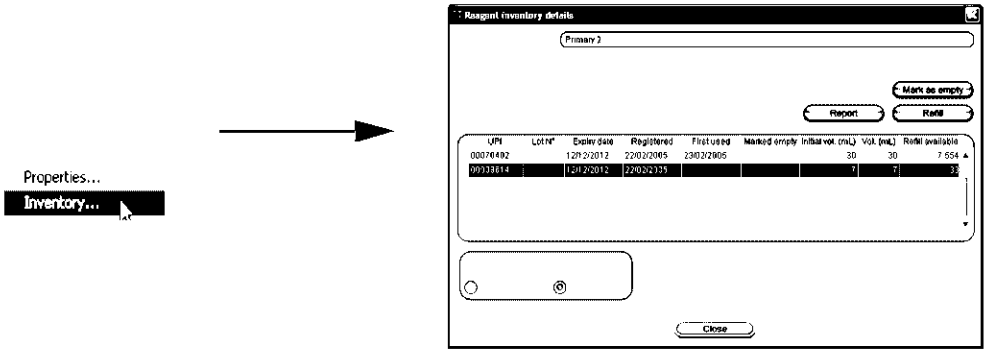


Figure 80: Showing the inventory from the status screen

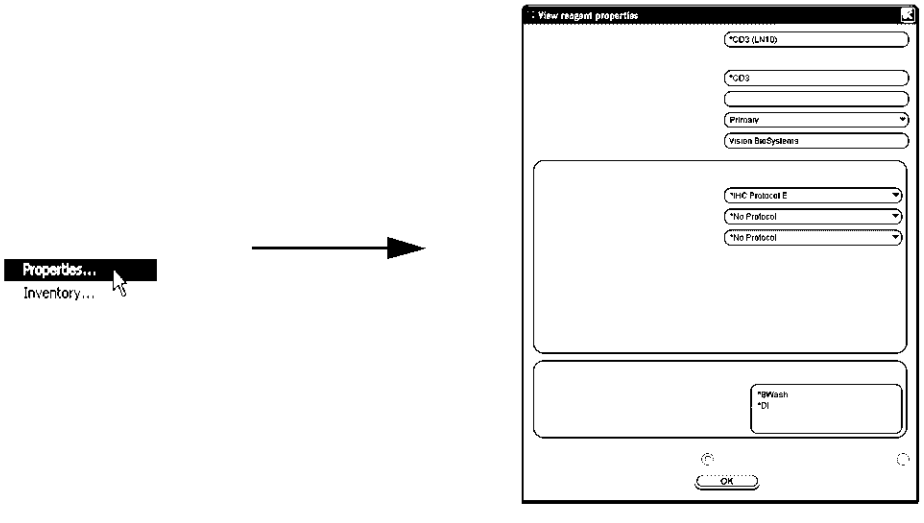


Figure 81: Showing the properties of a reagent

fixing reagent problems

If the Bond software detects a problem with a reagent required for processing, then the software will display an attention icon on a reagent container graphic below the slide batch displays on the System Status screen. To see more information about the problem, right-click on the attention icon.

If you need to replace or add reagent, remove the reagent tray containing the problem reagent, replace or add the required reagent to the tray, then reload the tray.

Note that if processing is already in progress, and reagent in a specific rack will be required within 2 minutes, you will not be able to remove that rack without abandoning the run.
This is indicated by the indicator for that tray glowing red.

fixing undetected reagents

If there is a reagent container there, check that the reagent is registered in the Reagent inventory screen (see "reagent inventory screen" on page 160), then remove and replace the reagent tray, ensuring that the tray is upright and correctly positioned, and the reagent lid is open.

If a reagent is not detected, do the following:

1. Check that:
   - The reagent container is correctly positioned in the reagent tray
   - The reagent container lid is opened and clipped to the back of the container
   - There is an undamaged ID across the top front of the container.
2. Check that the reagent is registered in the inventory (see "reagent inventory screen" on page 160).
3. If the reagent is not registered, then register it as described in "registering reagents and detection systems" on page 163.
4. At this point you can either remove the reagent rack and reinsert it to make the system automatically identify the reagent rack again, or you can manually select the reagent.

   To manually select the reagent, right-click on the container icon on the status screen and click select "Select…" from the submenu. You can then enter the Unique Pack Identifier (UPI) of a registered reagent, and click **OK**.

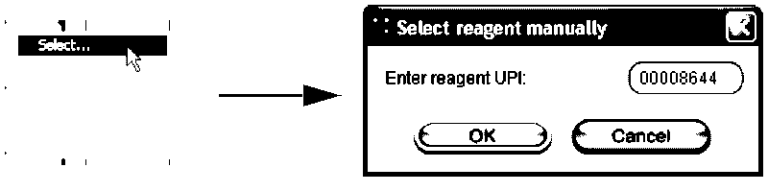


Figure 82: Selecting reagents manually

6.1.5 bulk container status

The bottom right of the status screen displays icons for bulk waste and reagent containers. Each container is labelled and the colors and sizes match the installed containers. Refer to "bulk containers cavity" on page 35 for the actual container configuration for each Processing Module type.

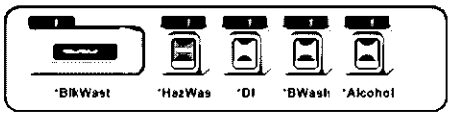


Figure 83: Bulk containers (Bond-x configuration)

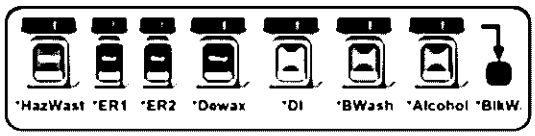


Figure 84: Bulk containers (Bond-max configuration)

The icon at the left is the external waste container icon.
The external waste container is a standard item with a Bond-max system, and an option with a Bond-x system.

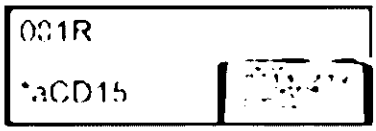
The software displays an attention icon over a bulk container when it detects a problem (for example, the volume in a reagent container is low, or the volume in a waste container is high). Right-click the notification icon for details.

Figure 85: Notification of bulk waste problem

6.1.6 slide information

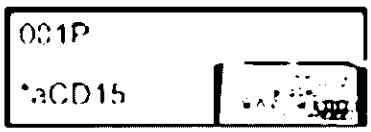
The status screen displays a graphical representation of each of the three slide trays with an icon for each slide. The slide icons indicate the state of each slide as shown in the following table.

No slide at this position

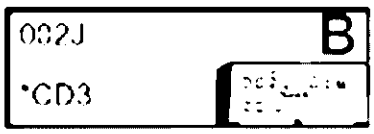


Slide imaged and automatically identified (refer to "automatic slide identification" on page 108)

Slide imaged but system unable to identify (the icon shows an image of the label area)



Slide imaged and manually identified (refer to "assisted slide identification" on page 109)



Slide is incompatible with one or more other slides on the tray (refer to "fixing incompatible slide setup" on page 111)

Slide processing (automatically identified)

Slide processing (manually identified)

Slide processing with event notification (refer to the following section "slide event notifications")

slide event notifications

Figure 86: Slide with event notification

When an unexpected event occurs during processing an alert symbol appears on the slide icon. This notification does not necessarily indicate that staining was in any way unsatisfactory. When the notification symbol appears the system operator or laboratory supervisor must take the following extra steps to confirm that the slide is suitable for diagnostic use.

1. Check the run events report (refer to "run events report" on page 178).
   Any events that caused a notification are displayed in **Bold** text. The system operator or laboratory supervisor should carefully consider the notification events listed as these provide important details about the nature of the slide notification events.
2. Carefully inspect the stained tissue.
3. Carefully inspect any control slides.

If the laboratory is unable to confirm the staining quality then either the pathologist should be informed of the notification or the test should be rerun.

automatic slide identification

The Bond system is able to automatically identify standard Bond slide labels created using the Bond labeller (as described in "slide labelling" on page 129). When a slide tray is locked, the system attempts to identify each slide label and match it against a slide that has had a label printed. Where it is able to match the label to a printed slide, the slide is automatically identified and no further action is required.

During the slide identification process the system captures an image of each label. These images appear in various reports to provide a permanent record of the slide matching.

If the system was unable to identify the label then the slide must be manually identified using the assisted slide identification procedure (see the next section).

assisted slide identification

If the Bond system is unable to automatically identify a slide, the slide can still be identified using the assisted slide identification procedure. This function allows the operator to match an image of the label to a slide in the slide list. Use the following procedure to manually identify a slide.

1. When the system is unable to automatically identify a slide the software displays an image of the label.

Figure 87: Slide not automatically identified
(in this example the label has been placed on the slide upsidedown)

2. To launch the assisted ID dialog do one of the following:
   (i) Double-click the slide image
   (ii) Right-click on the image and select "Select manually" from the submenu.
3. The "Slide identification" dialog will now appear.

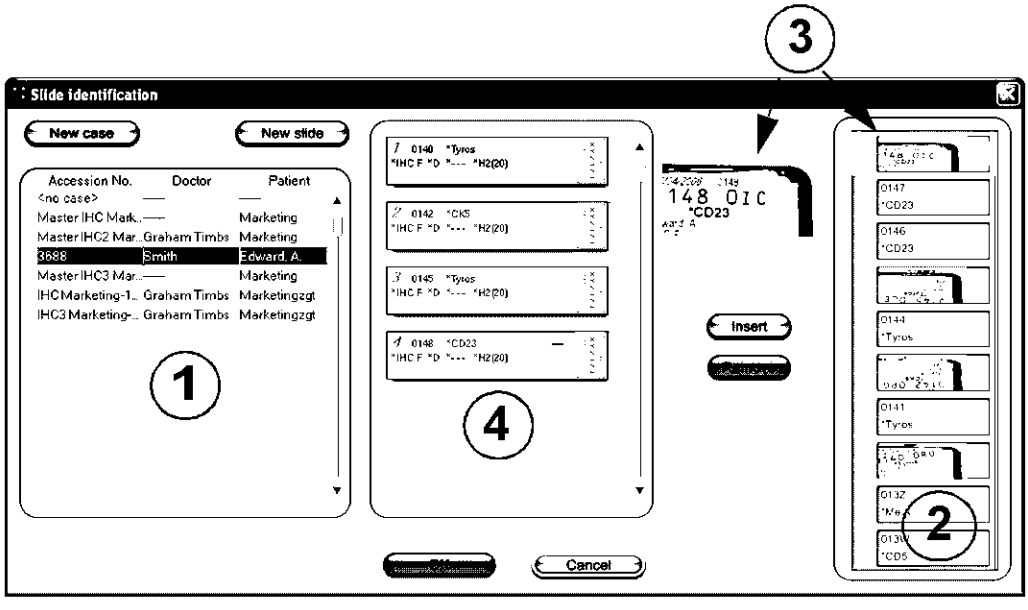


Figure 88: Slide identification dialog

The left-hand pane (item 1) lists all cases with current slides and empty cases that have not yet expired (see "case expiry" on page 123). Resurrected cases (see "case duplication and resurrection" on page 123) with no slides configured for them also appear, by default (see "setting new case and new slide options" on page 134).

Slide labels in the current Slide Staining Assembly are shown in the right-hand panel (item 2).

The slide selected when the dialog was opened is highlighted in the right-hand pane and displayed enlarged beside this (item 3). Hold the cursor over the slide in the right-hand pane to see an even bigger enlargement of the image.

The center panel (item 4) shows all the slides configured for the case currently selected in the left-hand pane that were not automatically matched, i.e. these slides were set up in the software but not identified in the Slide Staining Assembly when it was loaded.

It is possible to create new cases and slides at this point, with **New case** and **New slide**, if necessary (see "impromptu slide and case creation" on page 132 for instructions). The instructions below assume that all required slides are already configured in Bond.

4. Use the information visible in the selected label image, on the right, to determine the case that the slide belongs to. Select that case from the case pane (item 1).
   The slide list (item 4) is populated with the unmatched slides configured for that case.
5. Now match the unidentified slide to a slide in the slide list (item 4).

   Select the slide and press **Insert**.

   The slide is removed from the slide list and the image in the right-hand pane updates to show that the slide has been identified. A symbol identifies the slide as having been manually identified.

   The next unidentified slide label, if there are any, is now highlighted for identification.
6. Match all the unidentified slides by repeating the steps above.
7. When all the slides in the tray have been identified click **OK** to close the dialog.
   If you click **Cancel** any slide identifications you may have made will be lost.
8. The Status screen now shows all slides in the tray with their slide details. The slides that were manually identified include an image of the label and the symbol to show that the slide was manually selected.

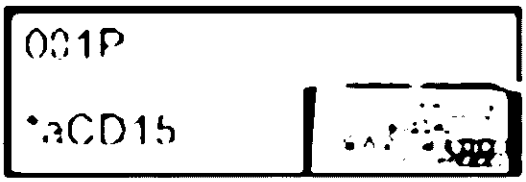


Figure 89: Manually processed slide prior to processing

9. Manually selected slides process normally.
   An image of the slide appears in various reports to provide a permanent record of the slide matching.

fixing incompatible slide setup

If the Bond system detects an incompatible slide, it will assign letters in bold red lettering at the upper right of all slides in the tray. Slides with the same letter are compatible. You must remove the slide tray and make sure that it contains only compatible slides.

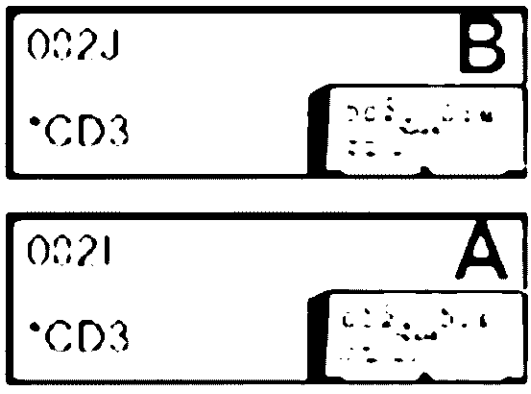


Figure 90: Incompatible slides

To remove a slide, press the button on the front panel associated with the tray containing the problem slide, remove the tray, remove the slide, replace the tray, then press the Load/Unload button again.

6.1.7 batch progress indicator

Batch progress indicators sit below each of the slide tray graphics. They provide a quick visual indication of batch status and progress.

batch status

The current batch number and batch status is displayed at the bottom of each progress indicator. The possible batch states are:

Unlocked	The slide tray is unlocked.
Locked	The slide tray is locked but it is not yet possible to start the batch. This state usually occurs prior to the completion of slide imaging.
Slides ready	All slides in the Slide Staining Assembly are recognized and ready for processing.
Starting	The start button has been pressed and the system is performing pre-start checks and scheduling.
Rejected/Slides ready	Bond attempted to start the batch but was unsuccessful. The most likely causes of rejection are missing reagents, low bulk reagent levels, or a full waste container. Check these and start again.
Scheduled	The batch is scheduled but has not started processing. The batch progress indicator indicates the scheduled start time.
Proc (OK)	The batch is processing, no unexpected events have occurred.
Proc (Notification)	The batch is processing, unexpected events have occurred. Check the "Run events" report for details.
Abandoning	The batch is being abandoned. This occurs when the operator presses the stop button.
Done (OK)	Processing is complete, no unexpected events occurred.
Done (Notification)	Processing is complete, unexpected events occurred. Check the "Run events" report for details.

batch progress

A progress bar below each slide tray graphic provides a visual display of batch progress. The progress bar displays critical times, shows the current progress with respect to the critical times, and uses the following colors to represent the four stages of batch progress:

- White — slide tray is locked, batch has not started
- Red — batch has not started and the starting time limit has been exceeded
- Green — batch processing
- Purple — batch has completed and is now being hydrated.

starting phase with no delayed start

During the starting phase for a run that does not use delayed start, the bar displays the following items (refer to Figure 91 for item numbers).

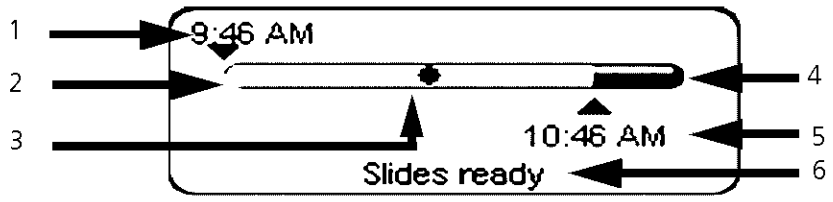


Figure 91: Batch progress (starting)

- Time the tray was locked (item 1)
- The acceptable starting period (white bar, item 2) (see "setting acceptable starting period & alarm" below)
- The current progress (item 3)
- The acceptable start time limit (item 5)
- The start time exceeded period (red bar, item 4)
- The batch status (item 6; see "batch status" above)

setting acceptable starting period & alarm

The acceptable starting period (timed from when the tray was locked) is user-configurable, set in the Options table (see "options table" on page 82). Separate periods can be entered for waxed and unwaxed slides.

For unwaxed slides you can also set an alarm, which should be configured to follow some time after the acceptable start time limit has passed (refer to "notifications, warnings and alarms" on page 52). This period too is timed from when the tray was locked.

Acceptable start time limits apply only to immediate-start batches; they do not apply to delayed start batches.

The Options table details are shown below.

Section	Key	Value	Default
ProtocolRules	acceptableBatchStartTimeLimit	Acceptable starting period (seconds) for unwaxed slides	900 (s)
ProtocolRules	acceptableBatchStartTimeLimitAlarm	Period from tray lock time (seconds) to alarm for unwaxed slides	1500 (s)
ProtocolRules	acceptableBatchStartTimeLimitDewax	Acceptable starting period (seconds) for waxed slides	3600 (s)

starting phase with delayed start

If delayed start is set, the bar displays the following items up until the run begins (refer to Figure 92 for item numbers).

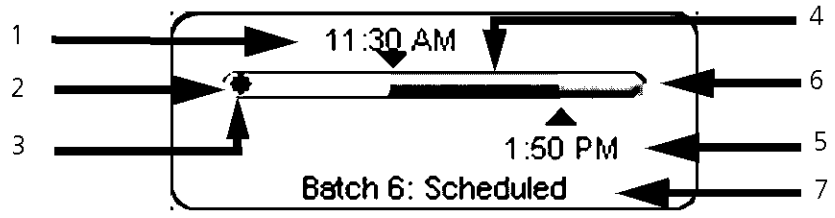


Figure 92: Batch progress (starting, with delayed start)

- Time the run is scheduled to start (item 1)
- Delay before the start (white bar, item 2)
- The current progress (item 3)
- Processing period (green bar, item 4)
- The approximate time the run will finish (item 5)
- Post processing hydration period (purple bar, item 6)
- The batch status (item 7; see "batch status" above)

during processing

During the processing phase the bar displays the following items (refer to Figure 93 for item numbers).

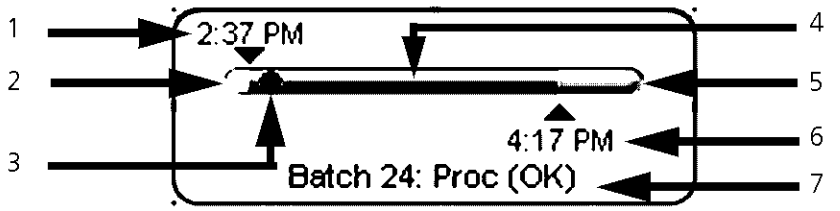


Figure 93: Batch progress (processing)

- Scheduled start time (item 1)
- The starting period (item 2) — white: start OK, red: start limit exceeded
- The current progress (item 3)
- Processing period (green bar, item 4)
- The end time (item 6)
- Post processing hydration period (purple bar, item 5)
- The batch status (item 7; see "batch status" above)

6.1.8 starting or stopping a run

You begin a run by loading and locking a slide tray. The tray is imaged and the system checks the following to ensure the batch can run:

- All slides are compatible
- All reagents are available.

When the batch is able to start, the batch status is set to "Slides ready" (refer to "batch status" on page 112) and the progress bar appears in the starting phase (refer to "batch progress" on page 112).

- To start the batch as soon as possible click ▶. For delayed start right-click on the tray and select "Delayed start" from the shortcut menu; see further directions in "delayed start" below)
  - The batch status is set to "Starting" as the pre-run checks and scheduling are completed. The progress bar remains in the starting phase.
  - Once the scheduling is complete, the state changes to "Scheduled".
    The progress bar now appears in the processing phase. The scheduled start time is displayed and the starting condition (OK or time limit exceeded) is displayed at the left end of the bar.
  - When processing starts at the scheduled time, the state changes to "Proc (OK)".
    If the start time limit was exceeded the warning or alarm clears once processing actually starts. The starting section of the progress bar remains red however.
  - Note that the "Starting" and "Scheduled" states may take some time and it is possible the starting time limit is exceeded. If this is likely to occur you can unlock the slide tray and manually re-hydrate the slides before restarting the batch. If you unlock a tray prior to processing commencing, the batch is not considered abandoned and can be restarted.

stopping a run

After pressing the start button (or activating delayed start) up until processing actually begins—while the batch is in "Starting" or "Scheduled" states—processing can be stopped for a batch without having to abandon it. To cancel a processing request at this time unlock the slide tray on the Processing Module (the start and abandon buttons are disabled during this period). Slide information remains in the system and the batch can be restarted later if you want. A single line is written to the Slide history list for the rejected batch.

To abandon a run once processing has started click ■. The Processing Module will cease operations after completing the current action (for example, dispensing or moving the aspirating probe). The slides in the tray are all lost from the system.

Consider carefully before abandoning a run—abandoned runs cannot be restarted, and you will lose any slides for which processing has not been completed.

6.1.9 delayed start

Bond-max Runs with waxed slides can be scheduled to start at a specified future time on the Bond-max system. Runs started overnight, for example, can be timed so that they finish shortly before start of work on the following day. Slides sit safely, still waxed, until processing begins, and the hydration period that follows processing is minimized.

Some non-Vision BioSystems reagents could deteriorate if kept for long periods on Processing Modules awaiting delayed starts. Check product data sheets for reagent use and storage information. As always, Vision BioSystems recommends placing control tissue on slides with test tissue.

setting delayed start time

To run a batch with delayed start, prepare slides as usual and lock the slide tray. Once the batch status is "Slides ready" select Delayed start from the tray shortcut menu on the System status screen.

Set the date and time that you want the batch to start in the Delayed start dialog, and click OK (see "using the date & time selector" on page 174). The system goes into "Starting" state as usual, and schedules the run in coordination with other operations. The batch then waits with status "Scheduled" until the set start time, when normal processing begins.

6.2 protocol status screen

This screen displays detailed information about the status of individual slides.
To display the Protocol status screen, go to the System status screen and click the Protocol status tab.

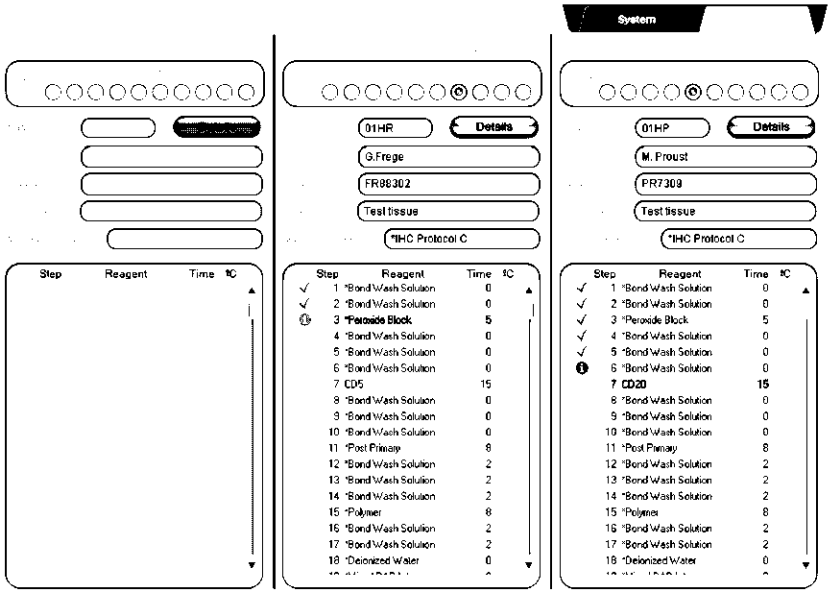


Figure 94: The Protocol status screen

To see how a run is progressing on a slide, click one of the radio buttons near the top of the screen. Radio buttons corresponding to positions without a slide are dimmed, and you cannot select them.

When you select a slide position, the software displays some slide details and the protocol progress. To view additional slide details select **Details** to launch the slide properties dialog.

The protocol steps for the selected slide are displayed beneath the slide details. The current step is highlighted green. Completed steps show a green tick, or if unexpected events occurred, an ⓘ icon. If all the required actions for the current step have been performed but there is a waiting period before the next step begins, the tick or ⓘ is gray. It remains gray until the next step starts, when it changes to the normal green or blue.

In the event of a power failure, you can review this screen to see which steps in the run were completed.

You can view run events and batch details for the batch by right-clicking the slide list and selecting *Show run events...* or *Show batch details...* from the submenu. You can also view service events in the same way, but the format is designed for use by service representatives only.

For information about history logs, refer to Chapter 10 "slide history".

7

slide setup

The standard workflow for creating slides for processing by Bond™ involves the following major steps:

1. Preparing the sections on the slides.
2. Creating a case for the slides in the Bond software (see "working with cases" on page 121).
3. Entering the details of the slides (see "working with slides" on page 125).
4. Labelling the slides (see "slide labelling" on page 129).
5. External processing (such as dewaxing and epitope retrieval).
   Not required with Bond-max Processing Modules as they can perform all common preparation steps.
6. Loading the slides on slide trays, and placing the slide trays in the Processing Module (see "loading slides" on page 94).

To start the standard workflow process, all protocols that will be used must be saved in the Bond software, all reagents that will be required should be available and registered, and the slides mounted with tissue should be available.

You should add control slides for processing with Bond according to the procedures in your own facility (see "working with controls" on page 119).

Once your slides have started processing, the Slide history screen allows you to produce a range of slide, case and batch reports. You can also add comments and a staining quality score to the history record of each slide. Refer to Chapter 10 "slide history" for details.

If the standard workflow does not suit your laboratory, there are alternative workflows. These are documented in the following sections:

- "impromptu slide and case creation" on page 132
- "daily case option" on page 135
- "alternative slide labelling options" on page 136.

7.1 slide setup screen

As the name implies, the Slide setup screen is where you tell the Bond software about the slides you are going to run on the Processing Module. This screen allows you to enter or modify details of cases and slides. Slides must belong to a case, so you must create a case before you can create slides. To display the Slide setup screen, click the Slide setup icon from the function bar.

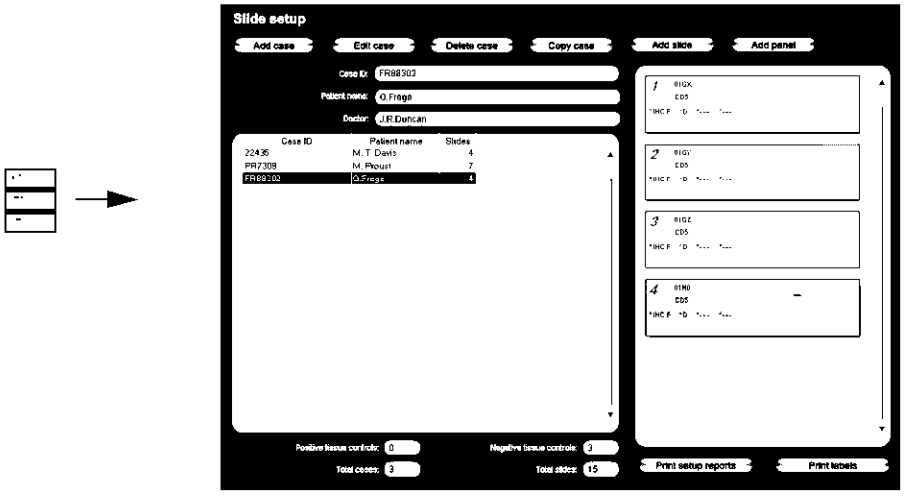


Figure 95: Click the Slide setup icon to display the Slide setup screen

Figure 95 shows the Slide setup screen. The left of the screen contains features for working with cases, the right of the screen contains features for working with slides.

7.2 working with controls

Vision BioSystems™ recommends routine use of controls on the Bond system. Bear in mind that controls should be a test of the whole process. This means using controls to check different batches of antibody, for example, as well as running controls for different protocols and batch runs on the Processing Module. See "quality control" on page 230 for further discussion.

To most adequately test the performance of your Bond system, we recommend placing control tissue on the same slide as the sample.

While placement of control tissue with test tissue is recommended, the Bond software allows a variety of alternative ways to set up controls, for both control tissue and control reagent. Users may find these convenient for their particular workflows, but should take care that control tissue slides are well marked to avoid confusion with patient test samples.

7.2.1 control tissue

Each slide must be entered into the Bond software as having one of the following tissue types:

- Test tissue
- Negative tissue
- Positive tissue

These are set with radio option buttons in the Add slide dialog (see "creating a slide" on page 126)

To avoid the possibility of control tissue being mistaken as patient tissue, we strongly recommend that positive or negative control tissue slides be set up in their own "Control" case, created specially for this purpose, rather than being included in a standard patient case.

Whenever the tissue type is changed for a new slide in the Add slide dialog, the Marker field automatically clears, to help ensure that you select the correct marker for the tissue.

Slides with negative or positive tissue are marked with a "–" or "+" respectively in the Slide setup screen. On the slide history screen, "Test", "Negative" or "Positive" is displayed for each slide in the Type column.

So that the slides themselves stand out clearly as controls, we include "TissueType" as one of the information fields in the default label layouts. This prints a large "(+)" on positive tissue control labels, and "(–)" on negative tissue control labels. Nothing is printed in the field for test tissue. We recommend including this field in any other slide labels you configure (see "slide label configuration" on page 67).

7.2.2 control reagent

Slides are set up with a control reagent by selecting the appropriate reagent as the marker, in place of standard antibodies or probes, during slide configuration.

For IHC, the Bond software includes a negative control reagent. With IHC selected in the Add slide dialog, select "*Negative" from the Marker drop-down list. By default Bond delivers Bond Wash Solution for these steps, but can be set to deliver deionized water by authorized service personnel. See "negative reagent control for IHC" on page 231 for further information.

For ISH, the Bond software includes both a negative and a positive control reagent. Select "*RNA Positive Control Probe" or "*RNA Negative Control Probe", as appropriate from the Marker drop-down list.

Slides with control reagents are not specially marked other than by the marker name shown in the slide setup screen and in the default label layout.

7.3 working with cases

This section describes the features at the left of the Slide setup screen that allow you to work with cases. The subsections following the descriptive section gives procedures for adding, editing, and deleting case details.

The Bond system assigns a unique identification number to every case created within that system. This number is the *Case No* and it is displayed in a non-editable field. In contrast, *Case ID* values are not necessarily unique.

7.3.1 description of case fields and controls

Click **Add case** to add details of a new case.
"adding a case" on page 122 describes the process.

Click **Edit case** to edit details of an existing case.
"editing a case" on page 123 describes the process.

Click **Delete case** to delete an existing case.
"deleting a case" on page 124 describes how to delete a case.

Click **Copy case** to add a copy of a case and the slides for that case.
"copying a case" on page 124 describes how to copy a case.

Three fields below the buttons contain information about the case selected in the list below.

Case ID	The case identification. This can be any alphanumeric character. Because this field can contain letters as well as numbers, clicking on the table heading sorts this field as text—an identifier beginning with "10" will be sorted ahead of an identifier beginning with "2".
Patient name	Identification of the patient.
Doctor	Name of the doctor or referring pathologist in charge of the patient.

The active case list is below the case information fields. As well as the *Case ID* and *Patient name* fields it contains:

No	This is the number of slides configured for the selected case. Once processing starts on slides they are moved from the Slide setup screen to the Slide history screen, and this number updates accordingly.

A case highlighted in red indicates that it is a priority LIS slide (see "priority slides" on page 193).

Beneath the active case list there is a summary of all cases and slides as follows:

Positive controls	The total number of positive tissue controls for all cases currently entered and not run.
Negative controls	Total number of negative tissue controls for all cases currently entered and not run.
Total cases	The total number of active cases.
Total slides	The total number of slides for all cases currently entered and not run.

7.3.2 adding a case

The Bond system generates a unique case number (Case *N°*) for that system whenever a new case is added. The same case identification (Case ID) may be used for different cases but each case has its own case number within a system.

To add a case, starting at the Slide setup screen, do the following:

1. Click **Add case** on the Slide setup screen to display the Add case dialog (see Figure 96).

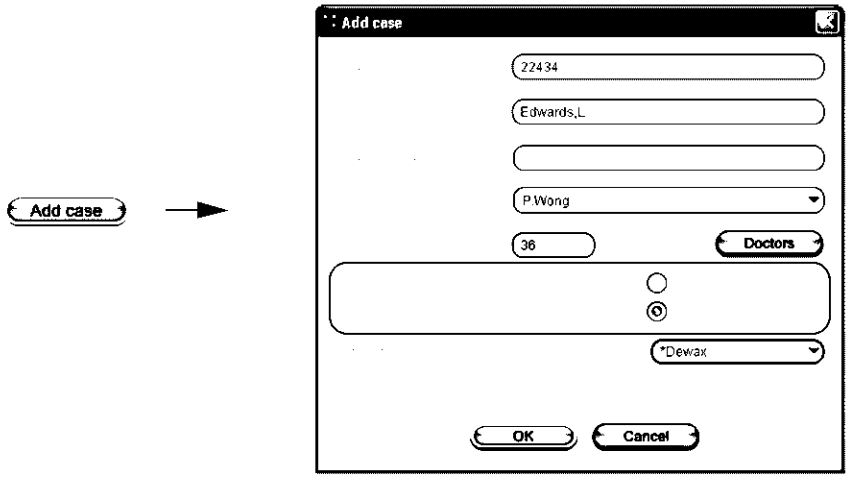


Figure 96: The Add case dialog
(Preparation option only applicable for Bond-max instruments)

2. Enter the details as appropriate in the *Case ID:*, *Patient name:*, *Case comment:*, and *Doctor:* fields.

It is possible to add cases without entering any information into any fields for a case.

3. If the doctor is not in the *Doctor:* drop-down list, you can add a new doctor to the Doctors list by clicking **Doctor**. This launches the Doctors list dialog (refer to "doctors list" on page 75).
4. Select a dispense volume to make it the default for slides created for this case.

   Note that all slides using ISH staining require 150 µL dispense volume.

   For information on the usable areas on slides for each dispense volume, refer to "slides" on page 41.

Bond-max

5. Select the preparation option from the Preparation drop-down list (see Figure 96) to include by default for slides created for this case.
6. To leave the dialog without entering the details in the system, click **Cancel**.
   To enter the details of the case, click **OK**.
7. The case is added to the case list.
   If the Case ID already exists in the system, the Case ID duplication dialog opens (see "case duplication and resurrection" below).

7.3.3 case duplication and resurrection

If, when adding a case, a Case ID that has already been used in the Bond system is entered, the Case ID duplication dialog is displayed listing the existing cases with the same *Case ID*. This dialog lets you create a new case (**Create new**) or use an existing case instead (**Use selected**, after selecting the case from the list). Alternatively you can close the Case ID duplication dialog without making a selection, and edit the case before attempting to save again.

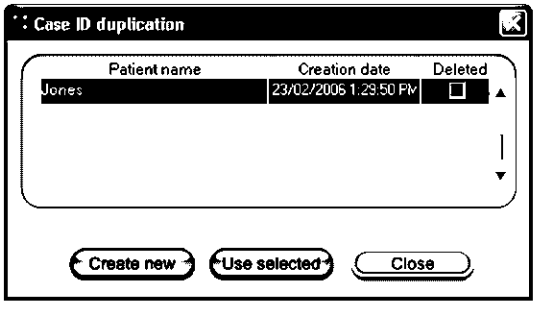


Figure 97: Case ID duplication dialog advising that the entered Case ID is not unique

The Case ID duplication dialog shows all cases that have ever been known to the system that have the same case ID.

When an expired case (see "case expiry" below) is selected from the Case ID duplication dialog and restored to the case list the case is said to be "resurrected".

7.3.4 case expiry

Cases are removed from the case list if they remain empty (have no slides) longer than the expiration time limit. The expiration time limit is configured from the options table (refer to "options table" on page 82). The option values are shown below.

Section	Key	Value	Default
ActiveCase	LifeTime	Time (in hours) a case remains active after either its creation or its last slide is started (whichever is later)	24

Case details remain stored in the system and the case is restored to the list if new slides belonging to the case are received (see "case duplication and resurrection" above).

7.3.5 editing a case

If you edit details of a case for which slide labels have been printed, print the labels again before attempting to run the slides.

To edit the details of a case, select it in the list then click **Edit case**. The software displays the Case properties dialog. You can use this in the same way as the Add case dialog described previously.

7.3.6 copying a case

Copying a case will create a duplicate of the case and also copy the slides for that case.
To copy a case:

1. Select the case to copy in the case list at the left of the Slide setup screen.
2. Click **Copy case**.
   The software displays the Copy case dialog.
3. Edit the details of the case as necessary, then click **OK**.

   If the Case ID is not unique, then a dialog is displayed (see Figure 97).

It is possible to duplicate a case and slides any number of times. The original case has the smallest case number of the set.

7.3.7 deleting a case

Deleting a case also deletes all slides created for that case.
You cannot recover the details of deleted cases or their slides.

To delete a case, select it in the list then click **Delete**. You will be asked to confirm your selection. Before clicking **OK**, look carefully at the row that is highlighted in the case list—it is this case that will be deleted.

You cannot delete a case for which any slides have begun processing.

7.4 working with slides

This section describes the features at the right of the Slide setup screen, which allow you to work with slides. The subsections following the descriptive section give procedures for adding, editing, and deleting slides.

7.4.1 description of slide fields and controls

At the top of the slide list there are two buttons:

- Click **Add slide** to add a slide for the selected case.
- Click **Add panel** to add a panel for the selected case.
  Refer to "adding a panel of slides" on page 128 for more details.

The slide list on the right of the screen displays details of slides for the case selected on the left of the screen. Each slide displays the slide ID and the details of the protocol to be run on that slide (see Figure 98).

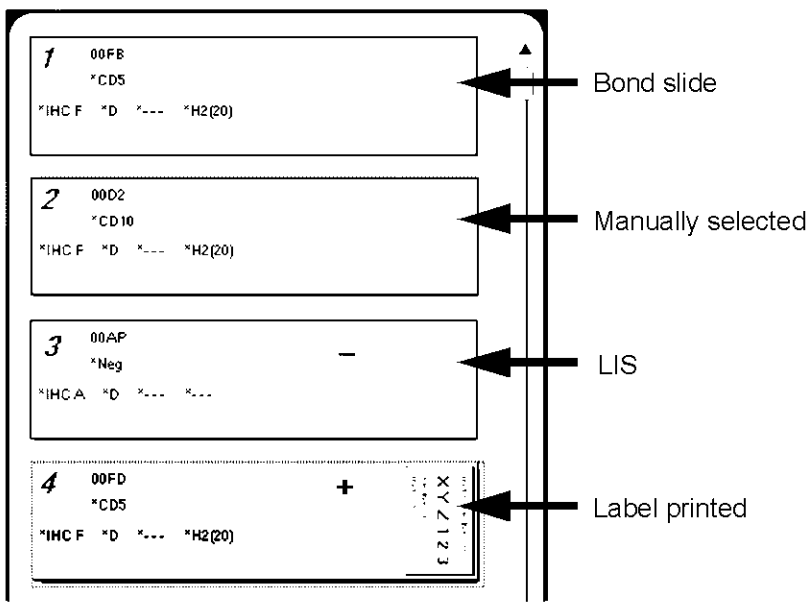


Figure 98: Part of a slide list

The label areas on the right of the slides are color-coded as follows:

- A white label area indicates that the slide was configured in Bond and automatically identified.
- A yellow label area indicates that the slide was manually selected (see "assisted slide identification" on page 109);
- A gray label area indicates that the slide was configured in an LIS (for systems with LIS-ip installed, see "LIS integration package" on page 189)

If labels have been printed for any of the slides, the slide is displayed with a sample label (see slide 4 in Figure 98).

If the slide is a tissue control, a "–" or "+" appears near the upper right of the slide (slides 3 and 4 in Figure 98).

Right-click on a slide and select "Slide properties" to see details about the slide.

7.4.2 creating a slide

To create a new slide:

1. Click on a case in the case list. (The case will be highlighted when it is selected.)
2. Click **Add slide** to display the Add slide dialog.
   The Add slide dialog has the same content as the Slide properties dialog, but with different command buttons at the bottom.

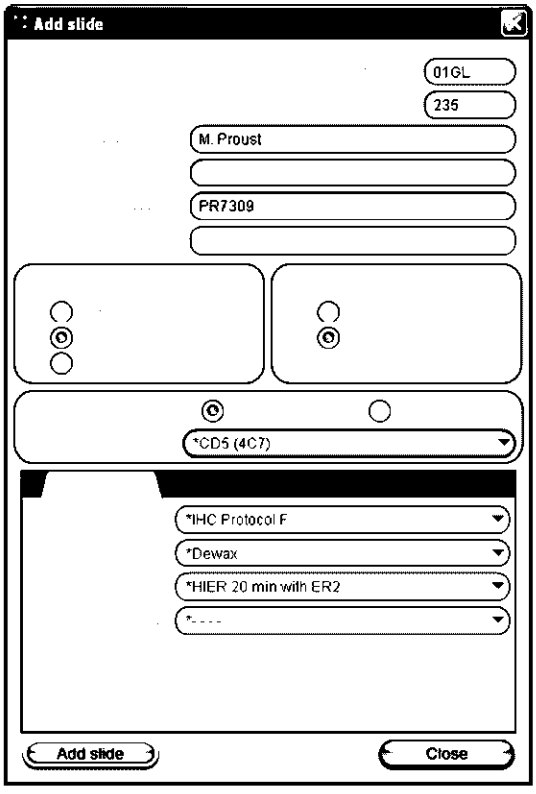


Figure 99: The Add slide dialog
(Dewax option only applicable for Bond-max instruments)

The new slide is automatically numbered with a four-character "Slide ID" in the top field. The Slide ID is unique for the Bond system you are working on.

Note that when a slide label is printed it uses the Slide ID and a three-character suffix, added to help ensure correct identification of the slide during imaging. The four-character ID is the full slide identifier used within the software, however.

3. Select the tissue type (Test tissue, Negative tissue, Positive tissue) by clicking one of the radio buttons in the *Tissue type* group.
   - Select "Test tissue" if the slide has a test sample.
   - Select "Negative tissue" if the slide has negative control tissue (refer to "negative tissue control" on page 231).
   - Select "Positive tissue" if the slide has positive control tissue (refer to "positive tissue control" on page 231, and "control tissue" on page 120).
4. If necessary change the dispense volume for the slide.

   The default is the setting selected for the case (see "adding a case" on page 122).

   Note that all slides using ISH staining require 150 µL dispense volume.

5. Select the staining process (IHC or ISH) then select the primary antibody or probe from the *Marker:* drop-down list.

   To run a negative IHC control reagent, select either the default negative reagent "*Negative" or a negative reagent you have created (refer to "negative reagent control for IHC" on page 231).

   To run a negative ISH control reagent select: *RNA Negative Control Probe.
   To run a positive ISH control reagent select: *RNA Positive Control Probe.

   To add or remove items from the *Marker:* drop-down list, select or deselect the *Preferred* field for the reagent on the Reagent setup screen of the software. See "adding or editing a reagent" on page 159 for more information.

   To add a number of slides quickly, you can add a panel (see "adding a panel of slides" on page 128). You can define your own panels. For an explanation of panels and how to create and use them, see "reagent panels screen" on page 170.

6. Select the appropriate protocol for each processing stage.
   When you select a primary antibody or a probe the software will enter default protocols. Check that the correct protocols are set for each stage and select a new protocol from the appropriate dialog if required. Select "*- - - -" if no protocol is required for a particular stage.

   Default protocols are set from the Reagent setup screen. Refer to "adding or editing a reagent" on page 159.

   To add or remove items from the *protocol* drop-down lists, select or deselect the *Preferred* field for the reagent on the Reagent setup screen of the software. See "adding or editing a reagent" on page 159 for more information.

7. Add a comment if you want, then click **Add slide.**

   Add slide adds a slide with the details currently displayed in the Add slide dialog, then leaves the dialog open. This make it easy to quickly add a number of slides for the selected case.

   To close the dialog without adding a slide, click **Close**.

7.4.3 copying a slide

To copy an existing slide, double-click it or right-click on it and select "Slide properties" from the submenu.

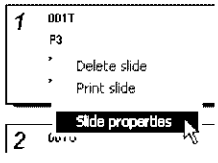


Figure 100: Right-click on a slide in the slide list to edit its properties

This opens the Slide properties dialog. Click **Copy slide** and the dialog changes to "Add slide", with an **Add slide** button. Press this to create a new slide with the same details but different Slide ID, or amend any of the settings before you create the new slide.

7.4.4 editing the details of an existing slide

To edit the details of a slide on the Slide setup screen, double-click it or right-click on it and select "Slide properties" from the submenu, as for copying a slide above. This opens the Slide properties dialog, and you can change the details as described in "creating a slide" on page 126.

If you edit details of a slide for which slide labels have been printed, you must print the labels again before attempting to run the slides.

7.4.5 deleting a slide

To remove a slide from the slide list, right-click it in the slide list on the Slide setup screen, then select **Delete slide** from the submenu.

7.4.6 adding a panel of slides

A panel is a user-defined set of markers and controls. Use panels to quickly add a number of slides.

For more information on panels, including details on how to define your own, refer to "reagent panels screen" on page 170.

To add a panel of slides to a case, do the following from the Slide setup screen:

1. Click **Add panel**. The Add panel dialog appears.

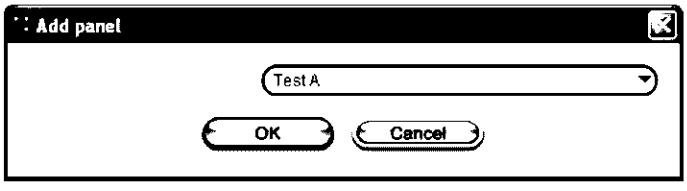


Figure 101: The Add panel dialog

2. Select a panel from the drop-down list, then click **OK**. Bond displays the panel marker selection dialog.

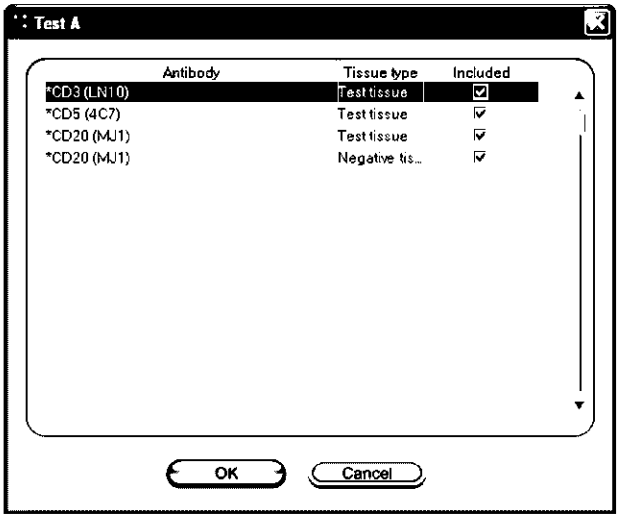


Figure 102: The panel marker selection dialog

3. If necessary, deselect some of the markers by clicking the check-boxes, then click **OK**.
   Bond adds the slides to the case.

   For ISH slides the dispense volume is automatically set to 150 µL.
   For IHC slides the dispense volume is set to the case default value.
   For all slides the preparation protocol is set to the case default.

7.5 slide identification

The Bond system provides a unique four-character "Slide ID" for each slide (i.e. unique within that Bond system). The slide ID makes up the first four characters of the label ID printed onto all Bond slide labels (the following three characters of the label ID provide an additional check on the slide's identification). When the labels are placed onto slides the system can identify the slides in each position in the Slide Staining Assemblies (refer to "automatic slide identification" on page 108).

Slides without slide IDs, or with unrecognized slide IDs, must either be manually identified to the system (refer to "assisted slide identification" on page 109), or a label printed and placed on the slide and the slide imaged again. Without this identification the slide cannot be run on the Bond system.

7.5.1 ad hoc slide identification

Any slide with a label printed by the Bond system can be identified at any time, from the Item ID menu. Select "Slide" from the menu, to open the Manual ID entry dialog.

Type the four-character slide ID into the field (the first four characters of the ID number on the slide label), and then press the Validate button. If that slide ID is known to the system, the Slide properties dialog for the slide opens, giving patient name, case ID, and staining details. See "slide properties, slide rerun and scoring" on page 175 for options available from this dialog.

7.5.2 slide labelling

You must use slide labels supplied by Vision BioSystems™ for use with the Bond slide labeller (see "slide label configuration" on page 67 for details of slide configuration options).

1. When all of your slides have been set up, click **Print labels** on the Slide setup screen.
2. Select whether to print slide labels for:
   - Current case — all slides for the currently selected case, including those previously printed
   - Slides not printed — slides in all cases for which labels have not been printed.

   Bond will print the labels in the same order they are displayed in the slide list.

   To print a label for a single slide, right-click on the slide, then select "Print slide".
3. Ensure the frosted area of the slide (where the label will be applied) is dry, then apply the label with the slide ID aligned with the end of the slide.
   Align the label squarely as the Processing Module cannot properly image misaligned labels.

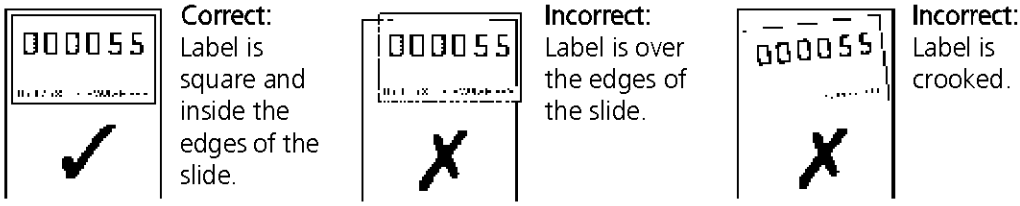


Figure 103: Place the label within the edges of the slide

Caution
Position all parts of the label within all slide edges. An exposed sticky surface may cause the slide label (and slide) to stick to the Covertile™ or other equipment and damage the slide.

7.6 slide setup reports

You must load slides so all slides on a tray are *compatible*. Slides are compatible if dispense volumes, dispense volume of the protocols, and the time and temperature for each step of the protocols being performed for all slides being stained are identical. If incompatible slides are loaded into the Processing Module on the same tray, the software will assign letters in bold red lettering at the upper right of all slides in the System status screen (refer to "fixing incompatible slide setup" on page 111).

Slide setup reports help you load slides on each tray so that they are compatible.
To print a Slide setup report, click **Print setup report**, then click the print icon . See "report printer configuration" on page 79 for further details.

A sample report (using the example in "case and test details for quick start" on page 87) is shown in Figure 104.

Slide setup reports will change as you enter and run slides. If you enter one batch of slides, then send them for dewaxing & epitope retrieval, print slide setup reports for this first batch before entering more slides.

User: jar

Slide setup summary

Slide ID	Marker	Staining protocol	HIER	Enzyme	Preparation	Dispense volume	Tissue
22435							
01BU	*CD23	*IHC F	*H2(20)	*- - - -	*- - - -	150 µL	Test
01BV	*CK5	*IHC F	*H2(20)	*- - - -	*- - - -	150 µL	Test
01BW	*CK5	*IHC F	*H2(20)	*- - - -	*- - - -	150 µL	Test
01BX	*MelA	*IHC F	*H2(20)	*- - - -	*- - - -	150 µL	Test
LM4569							
01BN	*CD10	*IHC F	*H2(20)	*- - - -	*- - - -	150 µL	Test
01BP	*CD10	*IHC F	*H2(20)	*- - - -	*- - - -	150 µL	Test
01BQ	*CD10	*IHC F	*H2(20)	*- - - -	*- - - -	150 µL	Negative
01BR	*CD20	*IHC F	*H1(20)	*- - - -	*- - - -	150 µL	Test
01BS	*CD3	*IHC F	*H2(20)	*- - - -	*- - - -	150 µL	Test
01CQ	*CD3	*IHC F	*H2(20)	*- - - -	*- - - -	150 µL	Test
01E0	*CD10	*IHC F	*H2(20)	*- - - -	*- - - -	150 µL	Negative
01E1	*CD10	*IHC F	*H2(20)	*- - - -	*- - - -	150 µL	Positive

Reagent summary	**Slides**
*CD10 (56C6)	5
*CD20 (MJ1)	1
*CD23 (1B12)	1
*CD3 (LN10)	2
*Cytokeratin 5 (XM26)	2
*Melan A (A103)	1
Bond Polymer Refine Detection	12

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Figure 104: Slide setup report

7.7 impromptu slide and case creation

By default, the Bond system is configured so that new cases and slides can be created after a slide tray has been loaded into a Processing Module and the slides imaged.

The first section below gives directions for this "impromptu" case and slide creation. The second section ("setting new case and new slide options" on page 134) describes option settings for a workflow that disallows impromptu case and slide creation.

7.7.1 creating new cases and/or slides after imaging

Using the default system settings, follow the procedure below to add case and slide information after slides have been loaded and imaged (the procedure is similar to the assisted-ID procedure described in "assisted slide identification" on page 109, but now includes creation of new cases and slides).

1. Load slides onto the Processing Module in the usual manner.
   There is no need to create cases or slides in the Bond software or print labels — hand written or third party labels can be used.
2. The system will not recognize the slides so will display images of the labels.

Figure 105: Slide not automatically identified

3. To launch the assisted ID dialog do one of the following:
   (i) Double-click on the slide image
   (ii) Right-click on the image and select "Select manually" from the submenu.

The "Slide identification" dialog appears with **New case** and **New slide** buttons available (items 1 & 2 in Figure 106).

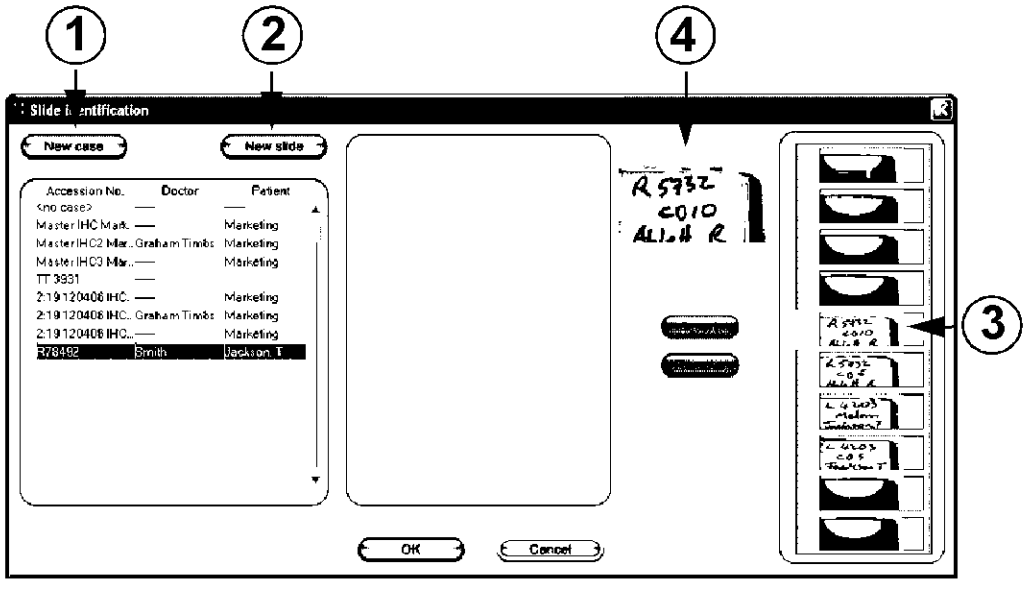


Figure 106: Slide identification dialog with slide status display

The active slide is highlighted on the slide tray (item 3).

The dialog includes an enlarged image of the label (item 4) to assist with slide identification. Hold the cursor over the slide in the right-hand pane to see an even greater enlargement of the label.

The left-hand pane lists all cases with current slides and empty cases that have not yet expired (see "case expiry" on page 123). Resurrected cases (see "case duplication and resurrection" on page 123) with no slides configured for them also appear, by default (see "setting new case and new slide options" on page 134).

The center pane shows any slides that have been configured for the case that is currently selected in the left-hand pane, and that have not yet been matched with any slides imaged on the Processing Module.

4. To create a new case, click **New case** (item 1).
5. You can now create a new case for the selected slide in the normal manner (refer to "adding a case" on page 122).
6. Once created the new case is automatically selected in the case list.
7. To create a new slide for the case you just created, click **New slide** (item 2).
   Note that this button becomes active when a case is selected.

   This opens the Add slide dialog.
8. Create a new slide in the software for the physical slide selected in the right-hand pane, in the normal manner (refer to "creating a slide" on page 126).

When it is added, the new slide is displayed in the center pane of the dialog (i.e. while the new case remains selected in the left-hand cases list). See Figure 107:.

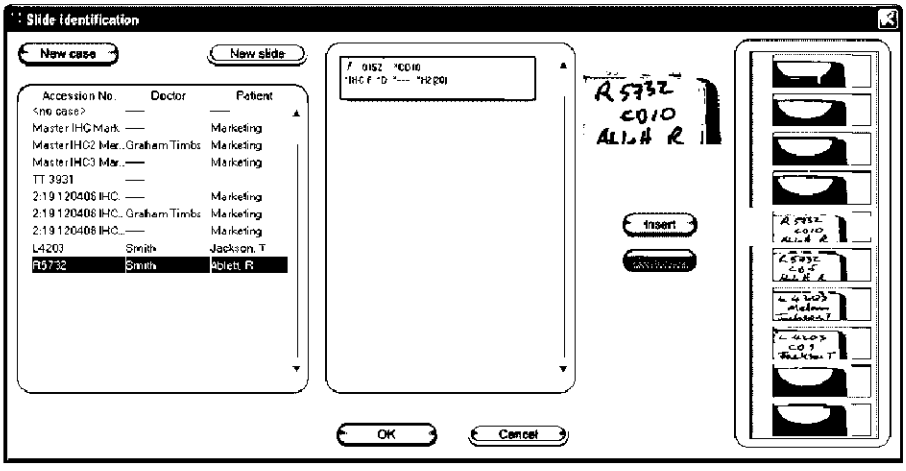


Figure 107: Newly created slide displayed in center pane

9. Ensuring that the correct label image is still selected in the right-hand pane, press **Insert** to match it with the new slide in the center pane.

   The slide is removed from the center pane and the label image in the right-hand pane replaced to show the system information for the slide, as it was entered for the new slide you have just created.

   If you match slides incorrectly, you can undo this step by selecting the slide in the right-hand pane and pressing **Remove**.

10. The slide can now be processed in the usual manner.
    Repeat the procedure of creating new cases and slides for remaining slides in the slide tray.

7.7.2 setting new case and new slide options

The options to create impromptu cases and slides in the Slide identification dialog after the physical slides have been imaged can be disabled in the Options table (refer to "options table" on page 82). You can remove just the option to create cases, still allowing new slide creation, or remove both options. The option values are shown below.

Section	Key	Value	Function
IdentificationOptions	CreateOnFly	CreateOnFlyNothing	No impromptu creation possible
		CreateOnFlySlide	Impromptu slide creation possible
		CreateOnFlyCaseSlide	Impromptu slide and case creation possible

Resurrected cases (see "case duplication and resurrection" on page 123) with no slides awaiting processing are not, by default, displayed in the case list, but can be included with a further Options table setting.

Section	Key	Value	Description
IdentificationOptions	ShowResurrected	ShowResurrectedOn	Shows resurrected cases with no slides in the Slide identification dialog
		ShowResurrectedOff (default)	Hides resurrected cases with no slides in the Slide identification dialog

Resurrected cases that have slides configured for them always appear in the Slide identification dialog.

7.8 daily case option

The Bond system can be configured so that Bond automatically creates a new case every 24 hours. This option is intended for laboratories that run a small number of slides (typically less than 60 per day) and do not need to record patient data on the Bond system. Each daily case has the following properties:

- The case ID is set to the new day's date
- Each case has a unique case number
- The dispense volume and preparation protocol default to the "Site preferences" settings and can be edited
- The *Patient name:* and *Doctor:* fields remain empty and cannot be altered.

The daily case option allows all slides for a particular day to be grouped under a common case and offers a fast method of setting up slides without entering any case data (i.e. patient ID, accession number etc.).

Daily case functionality can be set in the Options table (see "options table" on page 82).

Section	Key	Value	Function
IdentificationOptions	CreateDailyCase	CreateDailyCaseOff	Daily case functionality off (default)
		CreateDailyCaseOn	Daily case functionality on

7.9 alternative slide labelling options

The standard workflow of printing Bond slides for automatic recognition provides a fast and efficient way of running and identifying slides on the Bond system. However, Bond also accommodates alternative slide identification methods for laboratories that require slide labels to conform to other laboratory systems and who do not wish to double-label slides.

7.9.1 reconfigured bond slide labels

Bond slide labels can be configured so they comply with laboratory requirements that differ from the normal Bond configuration. These configurations may include re-arranged information, additional information and may even remove the information Bond needs to automatically recognize the slide. Where the slide labels do not include the normal Bond slide ID information, operators utilize the assisted-ID function to match slide labels to pending slides (refer to "assisted slide identification" on page 109).

Bond slide label layouts can be configured by users with Supervisor rights on the Bond software. Further configuration details can be found in "slide label configuration" on page 67.

7.9.2 external slide labels

According to the standard Bond workflow, Bond must print a label for a slide before the slide can be recognized and processed by the Bond system. This functionality is intended to reduce the possibility of human error when matching a slide on a Processing Module to the correct test data for that slide.

However, some laboratories prefer to have their slides labelled from an external source to better fit their overall workflow. Bond provides a configuration option for these laboratories that lets them use slide labels printed from a Laboratory Information System (LIS), third-party equipment or even hand-labelled slides. With this option enabled there is no need to print slide labels from Bond. When the slides are loaded onto a Processing Module the operator utilizes the assisted-ID function to match slide labels to pending slides (refer to "assisted slide identification" on page 109).

This option is configured from the options table (refer to "options table" on page 82). The option values are shown below.

Section	Key	Value	Function
IdentificationOptions	ForceNativePrinting	ForceNativePrintingOn	Bond must print a label before a Bond slide can run
		ForceNativePrintingOff	Slides can run without Bond printing a label

8

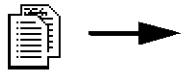
protocols

In the Bond™ software, protocols are the series of steps performed to stain tissue samples. These protocols are stored in the Bond software.

Your Bond system is supplied with a set of predefined "VBS" protocols that cannot be edited or deleted. However, you can create your own protocols by copying and editing existing protocols. These "User" protocols can be edited and deleted. Predefined protocols have an asterisk (*) as the first character in their name and abbreviated name. User protocols do not have an asterisk as the first character.

The predefined protocols have been rigorously tested and validated by Vision BioSystems™. They are known to produce excellent staining results when used correctly.
You must take responsibility for testing and validating any user protocol you create or edit. The ability to create and save a protocol does not indicate that it is suitable for the intended task.

To work with protocols, click the Protocol setup screen icon from the function bar.



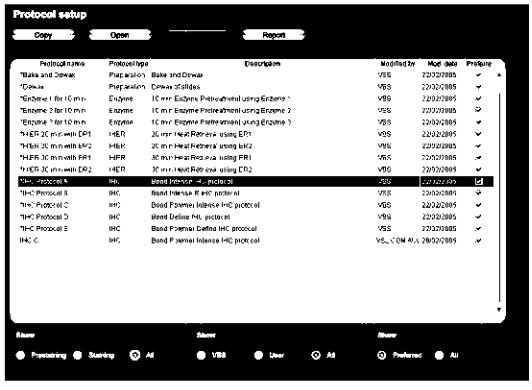


Figure 108: Protocol setup screen

Using this screen you are able to list, view, create, edit and delete protocols as well as produce protocol reports. Each of these functions is described in the following sections:

- "protocol types" on page 138
- "the protocol list" on page 138
- "viewing predefined protocols" on page 139
- "creating new protocols" on page 141
- "editing user protocols" on page 142
- "deleting protocols" on page 148
- "protocol reports" on page 149.

For a list of predefined protocols, please refer to "predefined protocol list" on page 151.

8.1 protocol types

The Bond protocols are categorized into types and groups according to their function. For each protocol type there are different step sequence and step parameter limits. The type also determines how the protocol may be used when setting up slides and cases. Once a protocol is created you can not alter its type and when copying existing protocols the type remains fixed. Thus to create a protocol, you must copy a protocol of the type you require.

The following table lists the protocol types and describes the function of each.

	Type	Group	Function
	IHC	Staining	Immunohistochemistry protocols for staining tissue.
Bond-max	ISH detection	Staining	In situ hybridization detection protocol
Bond-max	HIER	Pretreatment	Epitope retrieval using heat.
Bond-max	Enzyme	Pretreatment	Epitope retrieval using enzymes.
Bond-max	Dewax	Preparation	Dewax tissue.
Bond-max	Bake and dewax	Preparation	Bake slide (for tissue adhesion) then dewax tissue.

8.2 the protocol list

The Protocol setup screen has a table that lists each protocol along with some basic details. You are able to select a protocol from this table for other operations such as copying, editing and report generation. A blue highlight indicates the protocol currently selected.

Protocol name	Protocol type	Description	Modified by	Mod. date	Preferred
*Bake and Dewax	Preparation	Bake and Dewax	VBS	21/04/2006	✓
*Dewax	Preparation	Dewax of slides	VBS	21/04/2006	☑
*Enzyme 1 for 10 min	Pretreatment	10 min Enzyme Pretreatment using Enzyme 1	VBS	21/04/2006	✓
*Enzyme 1 for 15 min	Pretreatment	15 min Enzyme Pretreatment using Enzyme 1	VBS	21/04/2006	✓
*Enzyme 2 for 10 min	Pretreatment	10 min Enzyme Pretreatment using Enzyme 2	VBS	21/04/2006	✓
*Enzyme 2 for 15 min	Pretreatment	15 min Enzyme Pretreatment using Enzyme 2	VBS	21/04/2006	✓
*Enzyme 3 for 10 min	Pretreatment	10 min Enzyme Pretreatment using Enzyme 3	VBS	21/04/2006	✓
*Enzyme 3 for 15 min	Pretreatment	15 min Enzyme Pretreatment using Enzyme 3	VBS	21/04/2006	✓
*HIER 20 min with ER1	Pretreatment	20 min Heat Retrieval using ER1	VBS	21/04/2006	✓
*HIER 20 min with ER2	Pretreatment	20 min Heat Retrieval using ER2	VBS	21/04/2006	✓
*HIER 30 min with ER1	Pretreatment	30 min Heat Retrieval using ER1	VBS	21/04/2006	✓
*HIER 30 min with ER2	Pretreatment	30 min Heat Retrieval using ER2	VBS	21/04/2006	✓
*IHC Protocol A	IHC staining	Bond Intense IHC protocol	VBS	21/04/2006	✓
*IHC Protocol B	IHC staining	Bond Intense R IHC protocol	VBS	21/04/2006	✓
*IHC Protocol C	IHC staining	Bond Polymer Intense IHC protocol	VBS	21/04/2006	✓
*IHC Protocol D	IHC staining	Bond Define IHC protocol	VBS	21/04/2006	✓
*IHC Protocol E	IHC staining	Bond Polymer Define IHC protocol	VBS	21/04/2006	✓
*IHC Protocol F	IHC staining	Bond Polymer Refine IHC protocol	VBS	21/04/2006	✓
*IHC Protocol G	IHC staining	Bond Polymer AP Red IHC protocol	VBS	9/05/2006	✓
*ISH Protocol A	ISH detection	Bond Polymer Refine ISH protocol	VBS	21/04/2006	✓
*RNA Hybridization (2Hr)	ISH hybridization	RNA ISH Hybridization protocol	VBS	21/04/2006	✓

Figure 109: The protocol list

You are able to choose which protocols to include in the visible list using the *Show* radio buttons situated below the table.

Figure 110: Protocol "Show" radio buttons

The information in the protocol list is described below.

Title	Description	Options
Protocol name	Full name of the protocol	Predefined (VBS) protocols always begin with an asterisk(*)
Protocol type	Describes the function of the protocol	See "protocol types" on page 138
Description	Describes the protocol's function and application	
Modified by	Identifies who created or last modified the protocol	"VBS" indicates a predefined Vision BioSystems protocol
Mod. date	The date the protocol was created or last modified	
Preferred	Displays the protocol's preferred status	❑ Checked — this is a preferred protocol, available for selection in the Add slide dialog ❑ Not checked — this is not a preferred protocol, and is unavailable for selection in the Add slide dialog

8.3 viewing predefined protocols

You are able to view detailed information for each of the predefined protocols. Whilst viewing the protocol details you may also set the preferred status.

To open a predefined protocol for viewing, select the protocol from the list in the Protocol setup screen then click the **Open** button. The software displays the Edit protocol properties dialog but only the preferred setting is editable. To close this dialog, click the **Cancel** button.

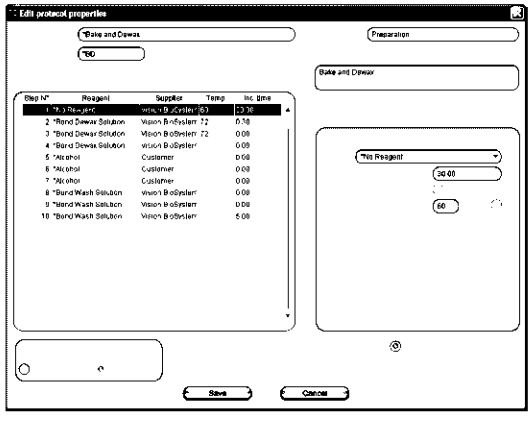


Figure 111: The Edit protocol properties dialog with a predefined protocol (some step details apply only to Bond-max protocols)

8.3.1 preferred status

To change the preferred status of the protocol, click the *Preferred:* radio button to toggle between preferred (button active) and non-preferred (button inactive).

8.3.2 general protocol information

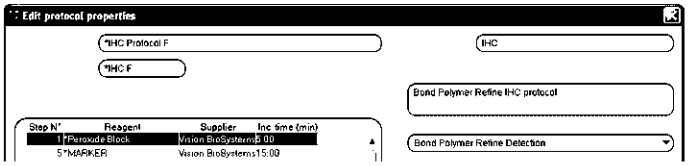


Figure 112: General information area

The Edit protocol properties dialog displays the following protocol information.
Note that none of these fields are editable for a predefined protocol.

Name	The protocol's full name.
Abbreviated name	The protocol's abbreviated name.
Protocol type	The type indicates the protocol's function and determines allowable steps and reagents.
Description	A brief statement describing the protocol.
Preferred detection system	The preferred detection system for this protocol. This does not apply to preparation or pretreatment protocols.

8.3.3 protocol step details

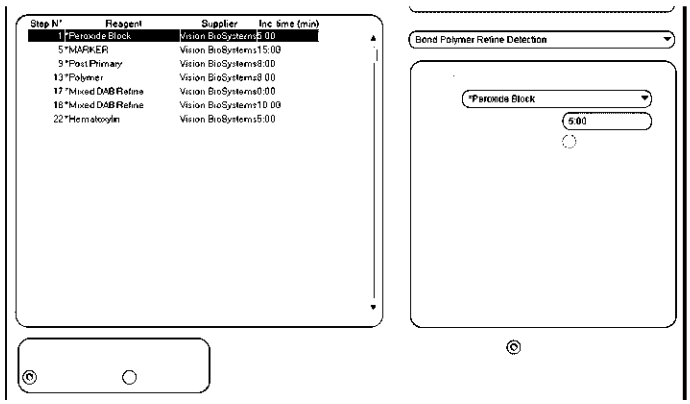


Figure 113: Protocol step list with Step details area and Show radio buttons

The Edit protocol properties dialog includes a table which lists each protocol step and its properties. You may choose to view all steps or you may hide the wash steps using the *Show* radio buttons below the table. By selecting a particular step in the table you may also view the step details in the "Step details" area.

The following information is available for each step. Note that none of these fields are editable for predefined protocols.

Area of dialog		Description
List	Step details	
Step No.	—	The order in which the steps of the protocol will be performed.
Reagent	Reagent	The reagent used in the step.
Supplier	—	The supplier of the reagent.
Temp. (°C)	Temperature (°C)	The slide temperature — either ambient or a selected temperature between 37 and 100 °C. These fields are only present for prestaining protocols.
Inc. time (min)	Incubation time (min)	The minimum time the reagent will remain on the slide.
—	Wash	When active, the radio button indicates a wash step.

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8.4 creating new protocols

You can create new protocols by copying existing user or Vision BioSystems protocols. When you copy a protocol, the type of protocol remains fixed and cannot be altered later. Thus if you wish to create a new IHC protocol you must copy an existing IHC protocol; for an HIER protocol, copy an existing HIER protocol and so on.

The ability to create and save a protocol does not indicate that it is suitable for the intended task. You must take the responsibility for testing and validating any protocol you create.

To copy a protocol, select it from the list in the Protocol setup screen then click the **Copy** button. A copy of the selected protocol will now appear in the New protocol properties dialog ready for editing.

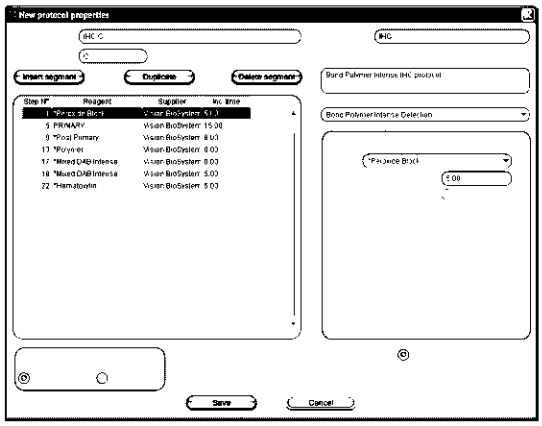

Figure 114: New protocol properties dialog
(some step details apply only to Bond-max protocols)

The new protocol will require a unique name and abbreviated name that must comply with all the rules specified in "protocol rules" on page 144. Other than changing the protocol's name and abbreviated name, you do not need to change any other part of your new protocol. However, you can, of course, alter any aspect of the protocol as described in "editing user protocols" on page 142.

To save the new protocol, click **Save** from the Edit protocol properties dialog. The save function checks the protocol against the protocol rules and will not allow you to save the changes if a rule is broken. Once a protocol complies with the rules, you will be asked to confirm that you are creating a protocol "at your own risk". This message is a reminder that Vision BioSystems cannot predict the quality of results from any user-created or edited protocol. Once you confirm that you are happy to continue, the protocol changes will be saved.

If you do not wish to save the new protocol, click **Cancel** at any time.

8.5 editing user protocols

You are able to edit any user protocol using the Edit protocol properties dialog. To edit a protocol select it from the list in the Protocol setup screen then click **Open**. The software displays the Edit protocol properties dialog, and allows you to edit the protocol's properties. If you wish to exit the dialog without saving or making any changes, click **Cancel**.

The ability to create and save a protocol does not indicate that it is suitable for the intended task. You must take the responsibility for testing and validating any protocol you create or edit.

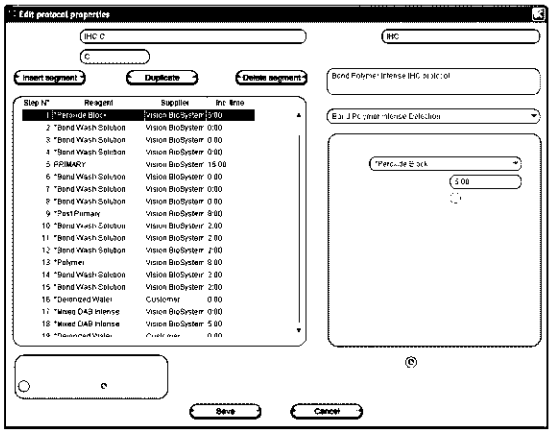

Figure 115: The Edit protocol properties dialog with an editable user protocol (some step details apply only to Bond-max protocols)

8.5.1 basic operation

You are able to edit or insert protocol steps by selecting a step to edit or an insertion point in the protocol step list. During editing, you may choose to view all protocol steps or you may hide the wash steps using the *Show* radio buttons below the table.

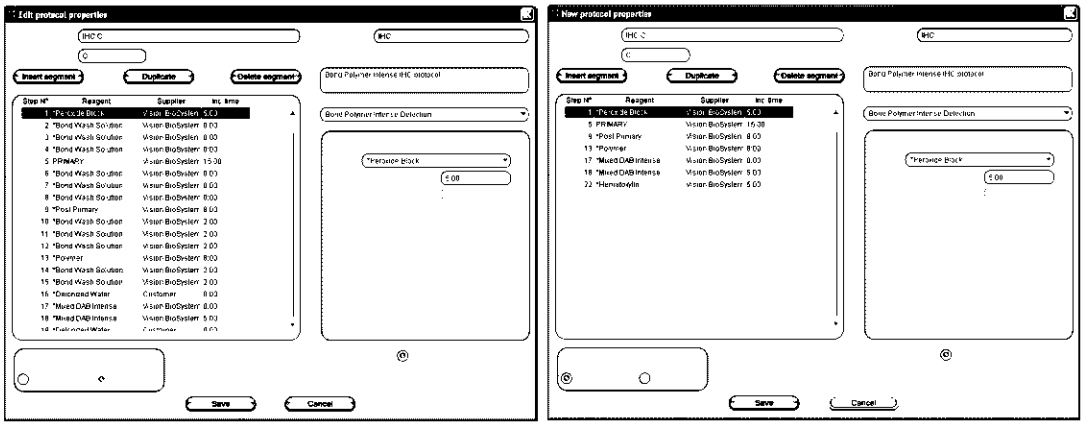

Figure 116: Protocol step list and Show radio buttons
(left - All steps shown; right - No Wash steps shown)

You are able to modify most aspects of a protocol so long as the changes comply with a set of protocol rules. As you edit a protocol, changed or new steps that have all the required information are shown highlighted in green. New steps that require additional information are highlighted in red.

To save any changes you make, click the **Save** button. The save function checks the protocol against the protocol rules and will not allow you to save the changes if a rule is broken. Once a protocol complies with the rules, you will be asked to confirm that you are creating a protocol "at your own risk". This message is a reminder that Vision BioSystems cannot predict the quality of results from any user-created or -edited protocol. Once you confirm that you are happy to continue, the protocol changes will be saved.

If you wish to exit the Edit protocol properties dialog without saving or making any changes, click **Cancel** at any time.

The various aspects of protocol editing are explained in the following sections:

- "protocol rules" on page 144
- "preferred status" on page 144.
- "editing general protocol information" on page 145
- "editing protocol steps" on page 145
- "adding and removing protocol steps" on page 146

8.5.2 protocol rules

Any protocol you create or edit must conform to some basic rules before it can be saved. Please note that these rules do not guarantee that the protocol will produce acceptable results when used.

The protocols rules are described in the following points.

1. The protocol name must not:
   (i) Begin with an asterisk
   (ii) Begin with a space
   (iii) Contain more than 23 characters.
2. The protocol name must be unique.
3. The protocol's abbreviated name must not:
   (i) Begin with an asterisk
   (ii) Begin with a space
   (iii) Contain more than 3 characters (preparation protocols), 6 characters (pretreatment protocols), or 8 characters (staining protocols).
4. The protocol's abbreviated name must be unique.
5. All IHC protocols must include a marker.
6. All staining protocols must include at least one reagent from a Vision BioSystems detection system.
7. For staining protocols, each reagent step must be followed by either a wash step or the same reagent.
8. For staining protocols, the last step must be a wash step.
9. For staining protocols, all step temperatures must be ambient.
10. For staining protocols, incubation times must be no longer than 30 minutes.
    Times greater than this may cause the tissue to dry out.
11. For pretreatment protocols, step temperatures must be either ambient or set to between 37 °C and 100 °C.
12. Each step must be fully defined with a reagent, incubation time and (where applicable) temperature.
13. Only one mixed reagent (e.g. mixed DAB) is allowed for each protocol.
14. The mixed reagent can only be used for two steps.

8.5.3 preferred status

To change the preferred status of a user protocol, click the *Preferred:* radio button to toggle between preferred (button active) and non-preferred (button inactive).

8.5.4 editing general protocol information

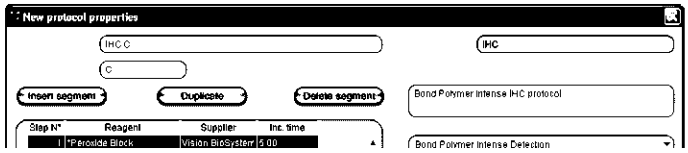

Figure 117: General information area

The Edit protocol properties dialog allows you to edit or view the following protocol information.

Name	The protocol's full name (only editable when the protocol is first created; see "protocol rules" on page 144).
Abbreviated name	The protocol's abbreviated name (only editable when the protocol is first created; see "protocol rules" on page 144).
Protocol type	The type indicates the protocol's function and determines allowable steps and reagents. This is not editable.
Description	A brief statement describing the protocol.
Preferred detection system	The preferred detection system for this protocol. This does not apply to preparation or pretreatment protocols.

8.5.5 editing protocol steps

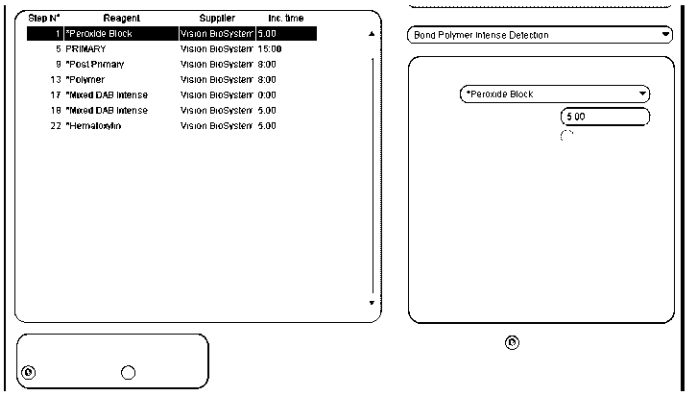

Figure 118: Protocol step list with Step details area and Show radio buttons

The Edit protocol properties dialog includes a table which lists each protocol step and its current properties. You may choose to view all steps or you may hide the wash steps using the *Show* radio buttons below the table. By selecting a particular step in the table you may edit the step in the "Step details" area. If you wish to add or remove steps, please refer to "adding and removing protocol steps" on page 146.

The editable parameters and acceptable values depend on the type of protocol being edited. Most parameters can be edited for IHC protocols. For pretreatment and preparation protocols, only incubation time (all steps) and step temperature (some steps) are editable.

The following information is available for each step and is editable where appropriate.

Area of dialog		Description
List	Step details	
Step	—	The order in which the steps of the protocol will be performed. Refer to the next section for adding and deleting steps.
Reagent	Reagent	The reagent used in the step.
Supplier	—	The supplier of the reagent. This is not editable.
Temp.	Temperature (°C)	The slide temperature — either ambient or a selected temperature between 37 and 100 °C.
Inc. Time	Incubation time (min)	The minimum time the reagent will remain on the slide.
—	Wash	When active, the radio button indicates a wash step.

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We recommend a second reagent dispense if incubation steps are more than 25 minutes.

8.5.6 adding and removing protocol steps

You may add and remove protocol steps in user IHC and ISH detection protocols. Pretreatment and preparation protocols have fixed step sequences that cannot be altered. Adding and removing steps is controlled by the three buttons that sit above the protocol list. These buttons are context sensitive and their availability and functions vary depending upon which step is currently selected.

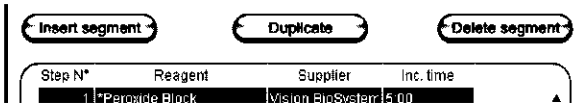

Figure 119: Step control buttons

You can add either single steps (where you wish to duplicate the current reagent or add a wash step) or you can add a reagent segment which includes a new reagent and the required wash steps. You may also delete either a duplicated step, an additional wash step or a reagent sequence (including the associated wash steps).

Refer to the following section for detailed instructions:

- "inserting a reagent segment" on page 147
- "duplicating a reagent step" on page 147
- "inserting an additional wash step" on page 147
- "deleting a reagent segment" on page 148.
- "deleting a duplicated reagent step" on page 148
- "deleting an additional wash step" on page 148

inserting a reagent segment

Use the following instructions to add a new reagent segment. This process adds a new reagent and the compulsory wash steps.

1. From the step list, select the insertion point (this must be a reagent).
   The new segment will normally be inserted above the selected reagent.
   If you select the last reagent, you will have the option of inserting the new segment above or below this reagent.
2. Click **Insert segment**.

   A new segment (with reagent and wash steps) will appear in the list.
   The wash steps will be highlighted green to indicate a change from the saved protocol.
   The reagent step will be selected, and therefore be highlighted blue, but when deselected the step is red to indicate that you must select a reagent for the step.
3. Ensure the new reagent step is selected. From the *Step details* area select the required reagent from the *Reagent:* drop-down list.
   Note: select "*MARKER" to indicate the step where the primary antibody is used in IHC protocols. There is no equivalent step type for ISH protocols, as probes are automatically applied prior to the staining protocol.
4. Edit other properties of the new reagent and wash steps as required.

duplicating a reagent step

Use the following instructions to duplicate a single existing reagent step.
Note that a duplicate step is one where two or more identical reagents follow each other without wash steps in between.

1. From the step list, select the reagent step you wish to duplicate.
2. Click the **Duplicate** button.
3. A new step with identical parameters to the current step will be added above the current step. The new step will be highlighted green to indicate a change from the saved protocol.
4. You can edit the step time for the new step.

If you change the reagent type of any duplicated step, all other reagent steps in the sequence will also change. This is because duplicate steps must use the same reagent.

inserting an additional wash step

Adding additional wash steps may alter the fluidic properties and lead to poor staining. Always validate new or edited protocols before diagnostic use.

Use the following instructions to insert an additional wash step.

1. From the step list, select an existing wash step.
   If you are unable to see wash steps, make sure you have elected to show all protocol steps with the *All* radio button at the bottom of the dialog.
2. Click **Insert wash**.

   A new wash step will be added at the end of the current wash sequence.
   The new step, when deselected, will be highlighted green to indicate a change from the saved protocol.
3. Modify the wash step parameters in the *Step details* area as required.
   Note that only Bond Wash Solution or deionized water can be used for wash steps.

deleting a reagent segment

Use the following instructions to delete a reagent segment. This procedure will remove the selected reagent and the associated wash steps.
Note that you cannot directly delete a segment with a duplicated reagent; you must delete the duplication first.

1. From the step list, select the reagent in the segment you wish to delete.
   This must not be a duplicated reagent.
2. Click **Delete segment**.

   The reagent segment (including all associated wash steps) will be removed from the step list.

deleting a duplicated reagent step

Use the following instructions to delete a duplicated reagent.

1. From the step list, select the duplicated reagent you wish to delete.
2. Click **Delete duplication**.

   The duplicated reagent will be removed from the step list.

deleting an additional wash step

Use the following instructions to delete an additional wash step.
Note that you can only remove wash steps that occur after the three compulsory wash steps in a wash sequence.

1. From the step list, select the additional wash step you wish to delete.
   This step must be after the three compulsory wash steps.
2. Click **Delete wash**.

   The additional wash step will be removed from the step list.

8.6 deleting protocols

To delete a user protocol, select it from the list in the Protocol setup screen and click **Delete**. Then, in the confirmation dialog, click **Yes** to confirm the deletion or **No** to leave the protocol in place.

Predefined Vision BioSystems protocols (starting with an asterisk) cannot be deleted.

Please note that you will not be able to generate protocol summary reports for deleted protocols.

8.7 protocol reports

This report displays the details of every step within the selected protocol. To generate a report, select a protocol from the list in the Protocol setup screen then click **Report**.

If the selected protocol has been modified then there is more than one version of the protocol. In this case, a Protocol reports dialog opens to allow you to choose from the Protocol version drop-down list the version to be reported. The original version is listed as "0", the default is the latest version shown as "--Current--". Click **Generate** to continue or **Close** to return to the Protocol setup screen.

The report is displayed in a new window (refer to Figure 120 on page 150 to view a sample report). The top right of the Protocol report shows the information in the following table.

Field	Description
Full name	The full name of the protocol.
ID	The unique identification number of the protocol.
Version	The selected version number of the protocol. The current version appends "(current)", previous versions append "(substituted)".
Type	The function of the protocol.
Created by	The identifier of the person who created the displayed version.
Creation time	The date and time the displayed version was created.
Facility	The name of the facility as entered in the Facility field of the Site Preferences dialog as described in "site preferences" on page 78.

The body of the report displays the following for each step:

- Reagent and supplier
- Step type
- Incubation time
- Temperature
- Dispense type

The footer of the report shows the time and date the report was printed, and the page number.

Click the print icon to obtain a copy of the report using the selected printer as described in "report printer configuration" on page 79.

sample protocol report

Full name: *IHC Protocol A
ID: 21
Version: 5 (current)
Type: IHC
Created by: VBS
Creation time: 22/02/2006 6:35 PM
Facility: VBS

Protocol: *IHC A

Step	Reagent		
1	*Peroxide Block	*Supplier:*	*Vision BioSystems*
Step type: Reagent step	Incubation time: 5 min 0 sec	Temperature: Ambient	Dispense type: Closed
Step	**Reagent**		
2	*Bond Wash Solution	*Supplier:*	*Vision BioSystems*
Step type: Wash step	Incubation time: 0 sec	Temperature: Ambient	Dispense type: Closed
Step	**Reagent**		
3	*Bond Wash Solution	*Supplier:*	*Vision BioSystems*
Step type: Wash step	Incubation time: 0 sec	Temperature: Ambient	Dispense type: Open
Step	**Reagent**		
4	*Bond Wash Solution	*Supplier:*	*Vision BioSystems*
Step type: Wash step	Incubation time: 0 sec	Temperature: Ambient	Dispense type: Closed
Step	**Reagent**		
5	Primary	*Supplier:*	*Not applicable*
Step type: Reagent step	Incubation time: 15 min 0 sec	Temperature: Ambient	Dispense type: Closed
Step	**Reagent**		
6	*Bond Wash Solution	*Supplier:*	*Vision BioSystems*
Step type: Wash step	Incubation time: 0 sec	Temperature: Ambient	Dispense type: Closed
Step	**Reagent**		
7	*Bond Wash Solution	*Supplier:*	*Vision BioSystems*
Step type: Wash step	Incubation time: 0 sec	Temperature: Ambient	Dispense type: Closed
Step	**Reagent**		
8	*Bond Wash Solution	*Supplier:*	*Vision BioSystems*
Step type: Wash step	Incubation time: 0 sec	Temperature: Ambient	Dispense type: Closed
Step	**Reagent**		
9	*Secondary Antibody	*Supplier:*	*Vision BioSystems*

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Figure 120: Protocol report

8.8 predefined protocol list

The following sections detail the predefined protocols that are supplied as part of the Bond software.

8.8.1 staining protocols

Each staining protocol is designed to use a particular Bond detection system. For detailed information on each detection system please refer to the literature accompanying each product or visit the Vision Biosystems web site: http://www.vision-bio.com.

You may use these protocols as the basic building blocks for your own tailored protocols by using the protocol editing functions (see "creating new protocols" on page 141 and "editing user protocols" on page 142).

Name	*IHC Protocol A
Type	IHC staining
Description	Bond Intense IHC protocol
Preferred detection system	Bond™ Intense Detection
Detection system notes	A biotin/streptavidin system that provides peroxide block, intense DAB staining, and hematoxylin counterstain (including bluing).

Name	*IHC Protocol B
Type	IHC staining
Description	Bond Intense R IHC protocol
Preferred detection system	Bond™ Intense R Detection
Detection system notes	A biotin/streptavidin system suitable for research applications that require an open choice of secondary antibody. It provides peroxide block, intense DAB staining and hematoxylin counterstain (including bluing).

Name	*IHC Protocol C
Type	IHC staining
Description	Bond Polymer Intense IHC protocol
Preferred detection system	Bond™ Polymer Intense Detection
Detection system notes	A high sensitivity compact polymer system that provides peroxide block, intense DAB staining, and hematoxylin counterstain (including bluing).

Name	*IHC Protocol D
Type	IHC staining
Description	Bond Define IHC protocol
Preferred detection system	Bond™ Define Detection
Detection system notes	A biotin/streptavidin system that provides peroxide block, crisp, well-defined DAB staining, and hematoxylin counterstain (including bluing). Especially suitable for clear delineation of membrane-bound antigens.

Name	*IHC Protocol E
Type	IHC staining
Description	Bond Polymer Define IHC protocol
Preferred detection system	Bond™ Polymer Define Detection
Detection system notes	A high sensitivity compact polymer system that provides peroxide block, crisp, well-defined DAB staining, and hematoxylin counterstain (including bluing). Especially suitable for clear delineation of membrane-bound antigens.

Name	*IHC Protocol F
Type	IHC staining
Description	Bond Polymer Refine IHC protocol
Preferred detection system	Bond™ Polymer Refine Detection
Detection system notes	A high amplification, biotin-free detection system optimized for use on the Bond system. Gives sharp definition of membrane-bound antigens with high intensity staining.

Name	*IHC Protocol G
Type	IHC staining
Description	Bond Polymer AP Red IHC protocol
Preferred detection system	Bond™ Polymer AP Red Detection
Detection system notes	A high sensitivity compact polymer system that provides bright red immunostaining through alkaline phosphatase, as well as hematoxylin counterstain (including bluing).

Name	*ISH Protocol A
Type	ISH detection
Description	Bond Polymer Refine ISH protocol
Preferred detection system	Bond™ Polymer Refine Detection
Detection system notes	A high sensitivity compact polymer system that provides peroxide block, crisp, well-defined DAB staining, and hematoxylin counterstain (including bluing).

8.8.2 pretreatment protocols

Bond-max The use of any particular pretreatment protocol is determined by the primary antibody or probe being used and also the tissue type.

You may use these protocols as the basic building blocks for your own tailored protocols by using the protocol editing functions. However you cannot alter the step sequences; only the step time and (where applicable) step temperatures are editable. Refer to "creating new protocols" on page 141 and "editing user protocols" on page 142 for details.

Name	*Enzyme 1 for 10 min
Type	Pretreatment
Description	10 min Enzyme Pretreatment using Enzyme 1

Name	*Enzyme 1 for 15 min
Type	Pretreatment
Description	15 min Enzyme Pretreatment using Enzyme 1

Name	*Enzyme 2 for 10 min
Type	Pretreatment
Description	10 min Enzyme Pretreatment using Enzyme 2

Name	*Enzyme 2 for 15 min
Type	Pretreatment
Description	15 min Enzyme Pretreatment using Enzyme 2

Name	*Enzyme 3 for 10 min
Type	Pretreatment
Description	10 min Enzyme Pretreatment using Enzyme 3

Name	*Enzyme 3 for 15 min
Type	Pretreatment
Description	15 min Enzyme Pretreatment using Enzyme 3

Name	*HIER 20 min with ER1
Type	Pretreatment
Description	20 min Heat Retrieval using ER1

Name	*HIER 20 min with ER2
Type	Pretreatment
Description	20 min Heat Retrieval using ER2

Name	*HIER 30 min with ER1
Type	Pretreatment
Description	30 min Heat Retrieval using ER1

Name	*HIER 30 min with ER2
Type	Pretreatment
Description	30 min Heat Retrieval using ER2

Name	*RNA Hybridization (2Hr)
Type	ISH hybridization
Description	RNA ISH Hybridization protocol

8.8.3 preparations

Bond-max These protocols allow you to dewax or bake and dewax slides on the Bond instrument (refer to "dewaxing and baking" on page 229 for additional details).
For bake and dewax protocols you may adjust the temperature and the length of the baking step but the step sequence and all other properties are fixed.
Whilst you can copy and rename dewax protocols, the step sequence and properties are fixed.

Name	Dewax
Type	Pretreatment
Description	Dewax slides

Name	Bake and Dewax
Type	Pretreatment
Description	Bake and dewax sides

9

reagent management

Management of Bond™ reagents is conducted using the three reagent management screens:

- The Setup screen is used to create and describe reagent types
  Refer to "reagent setup screen" on page 158
- The Inventory screen is used to administer actual reagent stocks
  Refer to "reagent inventory screen" on page 160
- The Panels screen is used to create marker groups that allow the quick addition of a standard diagnostic marker set to any case.
  Refer to "reagent panels screen" on page 170.

For an overview of Bond reagent management, refer to "reagent management overview" on page 156.

To open the reagent management screens, click on the reagents icon. From within this click on the tabs at the top right of the screen to open the required screen (Setup, Inventory and Panels).

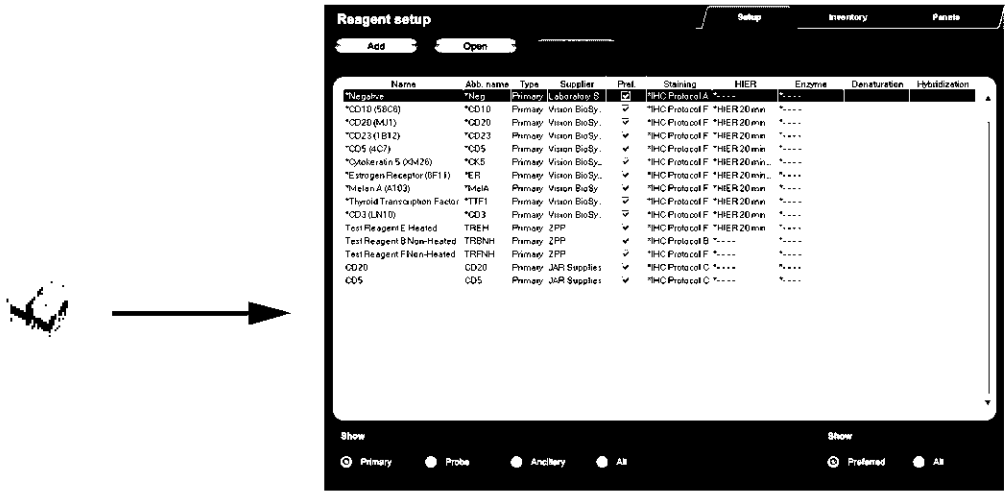

Figure 121: Click the Reagent screen icon to display the Reagent setup screen

Warning
Wear gloves when handling reagents and when opening reagent containers.
Reagent containers may be tipped during transport, possibly leaving reagent adhering to the lid.

9.1 reagent management overview

Running protocols on slides in the Bond Processing Module requires that physical amounts of reagents and detection systems in 7 mL and 30 mL containers are available. In order to use the reagent, Bond must have the details of these physical amounts of reagent added to the Reagent Inventory in the Bond software.

The Bond system comes with a number of predefined Vision BioSystems™ reagents and you can also add additional primary antibodies and ancillary reagents.
The process of adding reagent inventory to Bond is called registering reagents. Users should register all new reagents on receipt so that the Bond inventory shows the total stock of these.
As a reagent is used, Bond calculates the volume remaining. In addition, for reagents supplied by Vision BioSystems you can enter the stock volume at which you need to order more reagent.

Before you can register reagents, the Bond software must have details of the reagent, for example the reagent type and supplier. These details are entered in the Setup screen.
Bond is installed with a comprehensive list of reagents. Additional reagents, detection systems and titration containers must be added and registered before use.

9.1.1 reagent identification

Each reagent container is individually identified by a unique number called the Unique Pack Identifier (UPI). The UPI is read into the Bond software when the reagent package is scanned (or manually entered) when you register reagents into the Bond system (refer to "registering reagents and detection systems" on page 163).

You can display information about any reagent or detection system that has been registered, at any time, using the "Reagent or detection system" option in the Item ID menu. This opens the Manual ID entry dialog, where you can type in the UPI, or, after placing the cursor in the input field in the dialog, scanning it in.

With the UPI entered press **Validate**. If the system finds the reagent or kit in the database it will display all the information about it.

9.1.2 reagent substitution

Sufficient volume of all required reagents must be loaded onto the Processing Module before a slide batch can start. This should ensure that the batch is able to run to completion without running out of any particular reagent. Occasionally however a reagent that was initially present may not be available when needed. This may be because the operator has removed a reagent tray or a reagent container may have actually held less reagent than initially determined. If this occurs, Bond will attempt to substitute the missing reagent with reagent of the same type from a different container. The Bond system uses the following rules when substituting an unavailable reagent:

- The system initially tries to substitute the missing reagent with one of the same type from the same detection system.
  If successful the batch will continue without notification.
- The system then tries to substitute the missing reagent with an alternative source having the same type and the same Lot number.
  If successful the batch will continue without notification.
- The system then tries to substitute the missing reagent with an alternative source having the same reagent type but with any Lot number.
  If successful the batch will continue but affected slides will have an event notification.
- If reagent substitution is not possible, the reagent will be replaced by a bulk reagent for all dispenses to effected slides until the end of the batch.
  The batch will continue but affected slides will have an event notification.
- If all slides are affected and need to be replaced by a bulk reagent, the batch will be abandoned.

9.1.3 determining reagent volume

The Bond System uses two methods to establish reagent volume: it calculates it based on the initial reagent volume and it measures it using a Liquid Level Sensing (LLS) system that dips into a container to confirm the reagent volume.

The volume calculation relies on the initial reagent volume. This is accurate for detection system components and Vision BioSystems reagents as the containers are accurately filled during manufacture. Discrepancies can occur however if reagent is spilled, if sufficient reagent evaporates or if the reagent is used on another Bond system. The reagent volume in Bond open containers relies on accurate refill information and is also subject to the spill, evaporation and system usage discrepancies that apply to Vision BioSystems reagents and detection system components.

The LLS system is integrated into the aspirating probe. It determines reagent volume by detecting the height of the reagent when the aspirating probe dips into a container. LLS volume confirmation (often referred to as a "dip test") is used when the system has reason to question the calculated volume. To avoid unnecessary system delays it is not used constantly.

Dip tests will only be scheduled when they will not delay a batch start. Occasionally this may mean a reagent initially thought to be available may later be shown to have insufficient volume for scheduled batches. When this occurs an alarm will activate and the operator must either refill the container (open containers only) or ensure a suitable alternative reagent is available (refer to "reagent substitution" on page 157).

9.2 reagent setup screen

From this screen you can display and edit the details of reagents known to the Bond software.

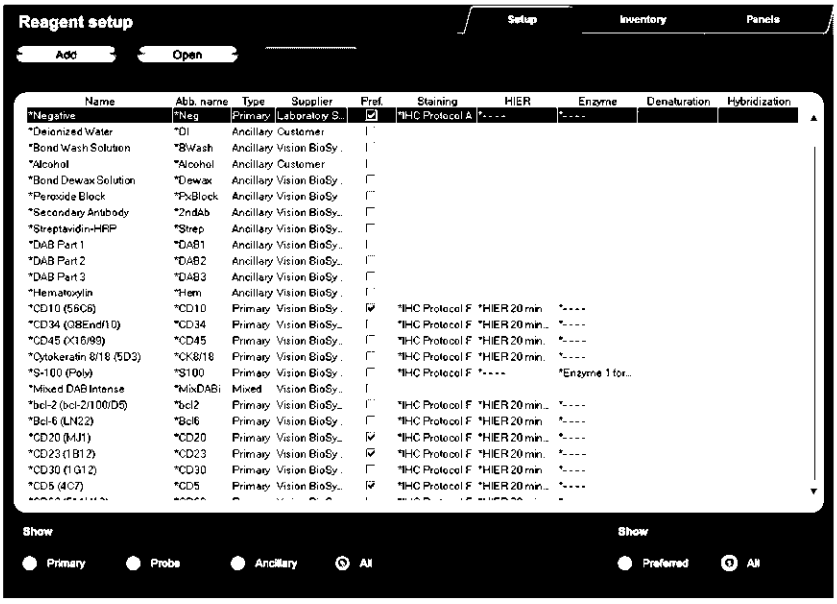

Figure 122: Reagent setup screen

The table displays the details of all reagents that Bond knows about—you cannot register reagents that are not listed here. Also, this screen does not tell you how much of each reagent is in stock. For details about inventory of reagents, refer to "reagent inventory screen" on page 160.

Buttons above the table allow you to: add new reagents; edit details of the reagent that is selected in the table; or delete the reagent that is selected in the table (you can only delete non-Vision BioSystems' reagents). Filters below the table allow you to see the type of reagent to display. The table contains the following details for each reagent:

Name	The full name of the reagent. An initial "*" character indicates a predefined Vision BioSystems reagent.
Abb. name	The short name of the reagent.
Type	The type of reagent, for example primary.
Supplier	The name of the supplier of the reagent.
Preferred	If this is ticked, then the reagent appears in the reagent drop-down list when you create or edit a protocol (see "editing user protocols" on page 142).
Default protocols	The protocols that are automatically added to the slide when the primary or probe is selected during slide setup.

These reagent details are entered when the reagents are added. Details are added and edited as described in "adding or editing a reagent" on page 159. When your Bond system is installed, a comprehensive list of reagents is installed with all of these details entered.

adding or editing a reagent

To tell the Bond software about reagents that do not appear in the reagent list, click **Add** in the Reagent Setup screen. Bond displays the Add Reagent dialog.
Note that you cannot add ISH probes as these must be supplied by Vision BioSystems.

To change the details of a reagent, select the reagent by clicking on it in the table, then click **Open**. The Edit reagent properties dialog opens. This is the same as the Add Reagent dialog with the details for the selected reagent entered.
Note that for predefined Vision BioSystems reagent only the default protocols are editable.

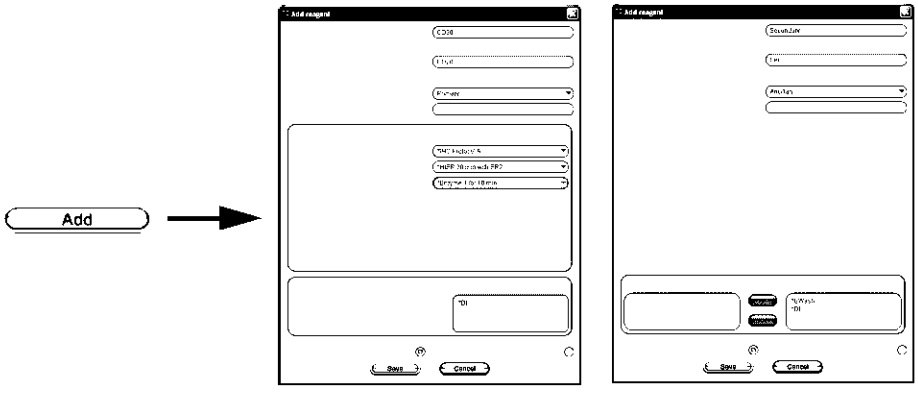

Figure 123: Add Reagent dialog (left - Primary; right - Ancillary)

1. Enter or edit a name for this reagent in the *Name:* field.

Be careful not to use a name that may cause this reagent to be confused with another when creating protocols or slides.

2. Enter a short name for the reagent in the *Abbreviated Name:* field.
   This is the label that appears on reagent icons in status screens.
3. If creating a new reagent, select the type of reagent from the *Type* drop-down list. This causes the editable fields to change depending on the type.
4. If the reagent is a marker you can select default protocols from drop-down lists.
5. If the reagent is an ancillary you can indicate which bulk solutions are compatible with it. Highlight the name of the bulk solution and click **>>** to move the solution into the *Compatible bulks:* list. Click **<<** to move the solution into the *Available bulks:* list if the solution is not compatible with the reagent.
   The Bond system takes appropriate action to ensure incompatible solutions do not come in contact with each other.

Caution
Unsatisfactory staining results and potential damage to the Processing Module can occur if incompatible solutions are allowed to come in contact with each other.
Consult with your reagent supplier to determine whether the solutions are compatible.

6. Enter the name of the supplier of the reagent in the *Supplier:* field.
7. Click *Preferred:* to display this reagent in slide setup dialogs.
8. Click *Hazardous:* if the reagent is to go into the hazardous waste disposal.
9. Click **Save** to add the reagent details to the Bond system.

Click **Cancel** at any time during the process to exit without making any changes.

deleting a reagent

To delete a reagent from the Bond system, select it in the table, then click **Delete**. You will be asked to confirm that you want to remove the reagent details from the system.

When you delete the details of a reagent, you also remove the inventory details for packages of this reagent.
You cannot recover deleted reagent details or inventory details.

9.3 reagent inventory screen

The inventory screen allows you to register reagents and detection systems, as well as change the details and minimum stock volumes of individual reagents registered. To display this screen, go to the Reagent setup screen, then click the Inventory tab.

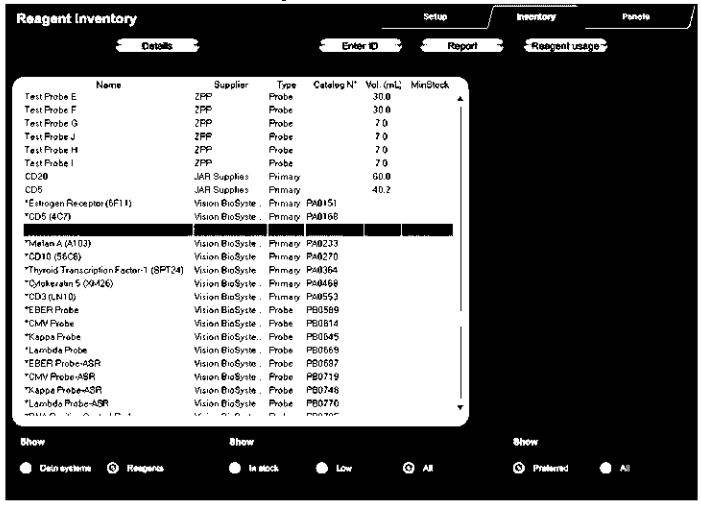

Figure 124: Reagent Inventory screen

The reagent table shows each reagent's *Name, Supplier, Type, and Catalog N°* as entered into the system when the reagent was added. The *Volume* field shows the total amount of the reagent that Bond software calculates is available. The *MinStock* field shows the minimum stock volume. Reagents that have less than the minimum stock volume are highlighted in red (refer to "changing the minimum stock volume setting" on page 162).

When displaying detection systems, the table displays *Name, Catalog N°, and Vol and MinStock* columns.

The radio buttons at the bottom of the table in the Reagent inventory screen determine what is displayed in the table:

- Select "Reagents" to show only reagents registered in the system, or "Detn systems" to show only detection systems registered in the system.
  Note that when viewing detection systems the other Show options are disabled and all detection systems are automatically displayed in the list.
- Select "In stock" to show only reagents for which there are volumes recorded, "Low" to show reagents that require re-ordering, or "All" to show all reagents registered with the Bond system, whether or not stock is held.
  These options do not affect detection system visibility.
- Select "Preferred" to show only those reagents set as preferred, or select "All" to show all reagents.
  These options do not affect detection system visibility.
  See "adding or editing a reagent" on page 159 for setting a reagent as preferred.

The control buttons above the reagent table allow you to manage the reagent inventory.

- Click **Details** to see the details of the reagent package selected in the table.
  See "reagent or detection system details" on page 162 for more information.
- Click **Enter ID** to add inventory of reagent to the system in the "Manual ID entry" dialog when the ID cannot be automatically recognized by the hand-held scanner.
  Refer to "registering reagents and detection systems" on page 163 for more information.
- Click **Report** to generate a report of those reagents or detection systems currently listed in the table.
  See "reporting reagent or detection system inventory" on page 166.
- Click **Reagent usage** to generate a report of reagent usage within a specified time period.
  See "reagent usage report" on page 168

Reagent inventory volumes may include volume remaining in detection systems marked as empty.

9.3.1 inventory tracking

The Reagent inventory screen shows the amount of each reagent in stock. You can also specify a minimum stock level for Vision BioSystems reagents supplied in prefilled containers. Each prefilled Vision BioSystems reagent that has less than the minimum stock volume is highlighted in red on the display. A report (see "reporting reagent or detection system inventory" on page 166) flags these reagents with "Low" shown next to the volume.

To enter the value for the minimum stock for each reagent, see the following section "reagent or detection system details".

9.3.2 reagent or detection system details

To display details of individual packages of a reagent, click on it in the table, then click **Details**.

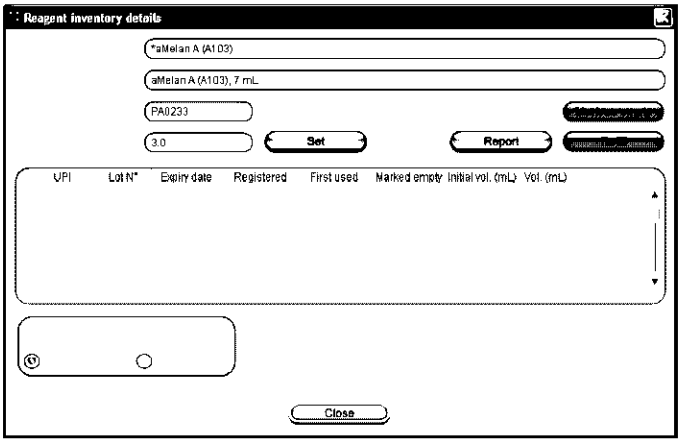

Figure 125: Reagent Inventory Details screen

The "Reagent inventory details" dialog displays each individual package of the selected reagent that has been registered in the Bond software. By default only packages with remaining volume are shown. To see all packages (including empty ones), click the *All* radio button below the table.

The reagent *Name, Package name, and Catalog N°* are entered when the reagent is entered. For details on adding and editing reagent details, see "reagent setup screen" on page 158.
The details for *UPI* (Unique Pack Identifier), *Lot N°, Expiry date, Registered,* and *Initial vol.* are entered by the software when the reagent is registered. *First used* is entered by the Bond software when the reagent is used for the first time. These details cannot be changed.
Marked empty is entered by the software when it detects an empty container or you select the package or detection system as empty (see "marking a package as empty or not empty" on page 163). The *Vol.* and *Refill available* fields are calculated by the Bond software.

The inventory details dialog for detection systems is similar to that for reagents, with the *Initial Vol* and *Refill available* columns being absent from the table, and the refill button is absent from the dialog.

refilling containers

Click **Refill** to tell the software that you have refilled an open container (see "refilling an open reagent container" on page 163 for details).

reagent report

Click **Report** to generate a report for just the selected reagent. See "reporting reagent or detection system inventory" on page 166 for more details.

changing the minimum stock volume setting

To change the minimum stock volume setting, click **Set.** This opens the Set minimum stock volume dialog. Enter the required minimum stock volume setting in the *Minimum stock* field. Click **OK** to set the value or **Cancel** to dismiss the box without making changes.

Note that minimum stock levels can only be set for Vision BioSystems prefilled reagents, they cannot be set for open containers.

marking a package as empty or not empty

You can mark a reagent package or detection system as empty, for example when a reagent is discarded before being completely used. To mark a reagent package or detection system as empty, select it in the table, then click **Mark as empty**. The software puts the current date in the *Marked empty* field.

To mark a reagent or detection system as not empty, select the package or system in the table and click **Mark as not empty**.
You may need to select the "All" radio button above the table first to show items that are marked as empty.

refilling an open reagent container

You can reuse Bond Open reagent containers to dispense up to 40 mL of a particular reagent. Use the following instructions to refill a open container.

1. Fill the container with the reagent.
   The reagent must be the same as that originally specified for the container when it was initially registered.
2. Scan the container (as described below in "registering reagents and detection systems") then click **Refill**.

   The refill button will not be available if putting more reagent into the container will exceed the 40 mL limit.

Each open container is locked to a particular reagent when it is first registered. Each open container must use the same reagent each time it is refilled.

9.3.3 registering reagents and detection systems

Registering a reagent adds a new package of reagent to the inventory. The reagent must be listed in the Reagent setup screen before you can register a package of it.

You must register reagent packages before using them on Bond.
If you load an unregistered reagent container in the Processing Module, the software will not recognize it, and display a "?" in that reagent position on the System status screen. For more information on the System status screen see "system status screen" on page 100.

Bond will track reagent usage and will alert you when the reagent must be replaced.
Do not attempt to refill a prefilled Bond reagent container as Bond will recognize that this is a used container and refuse to use it.

The methods for registering Bond reagents, Bond detection systems, and non-Bond reagents are described in the following sections:

- "registering bond detection systems" on page 164
- "registering Bond reagents" on page 164
- "registering non-bond reagents" on page 165
- "manual ID entry" on page 165.

registering bond detection systems

To register a Bond detection system, scan both IDs on the side of the reagent tray carrying the detection system containers.

Warning Laser hazard. Potential for severe eye damage. Avoid direct eye contact with laser beams.

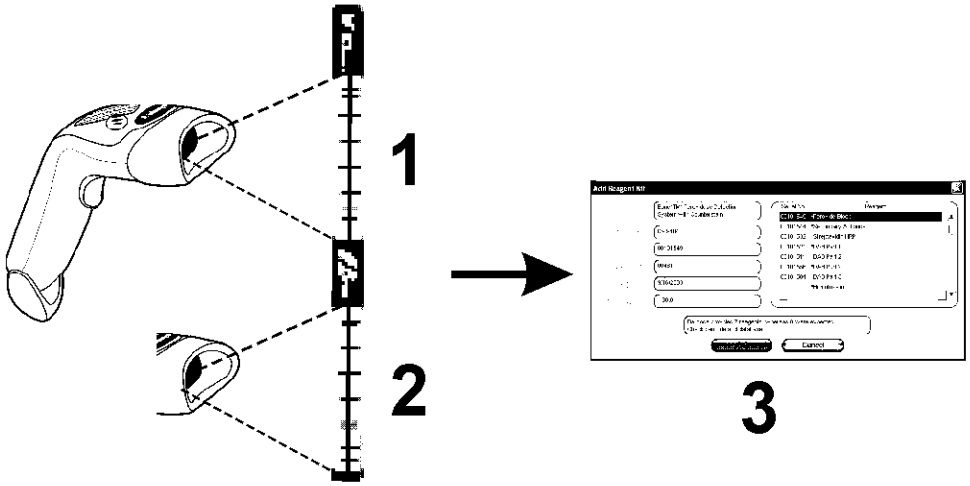

Figure 126: Registering Bond detection systems

Click **OK** to register the detection system.

Do not attempt to register individual reagent containers that are part of a detection system.

registering Bond reagents

To register a Bond reagent package, scan the ID on the side of the container. The software will display the Add reagent package dialog.

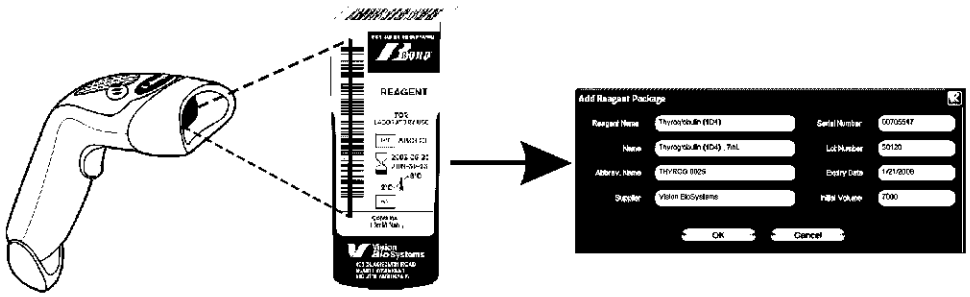

Figure 127: Registering Bond reagent packages

Check that the details in the dialog correspond to the details of the package, then click **OK**.

registering non-bond reagents

You must add the details of the reagent to the Bond system from the "reagent setup screen" before you can register physical amounts of it. For details of adding a reagent, see "adding or editing a reagent" on page 159.

You must use **non-Bond reagents** with a Bond Open Reagent Container, and you must register that container as for Bond reagent containers. When you read an open container ID, the Add Reagent Package dialog opens with the *Reagent Name* field blank. You must select a name from the drop-down list, fill in other fields as necessary (you must enter an expiry date), then click **OK**.

manual ID entry

In some cases IDs on reagent packages may become damaged to the point where the Bond system cannot read them. If the Bond system fails to read a reagent ID, do the following from the "reagent inventory screen":

1. Click **Enter ID**.
   The Bond software displays the Manual ID entry dialog.

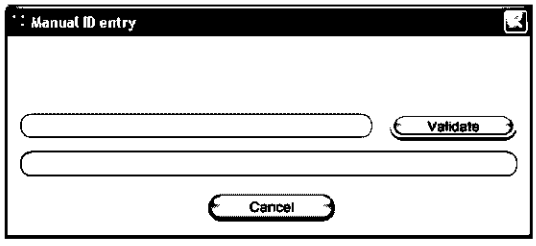

Figure 128: The Manual reagent ID entry dialog for registering reagents

2. Enter the package number in the top row.
   The package number is alongside the ID on reagent packages, and above the ID on detection systems.
3. If there is more than one ID, as for a detection system for example, then click **Validate** after entering each ID.

   The software will check the ID, and if it is valid, display the details of the package as for "registering Bond reagents" on page 164, or "registering bond detection systems" on page 164, or "registering non-bond reagents" on page 165.
4. Click **Close** when you have finished entering and checking the details.

9.3.4 reporting reagent or detection system inventory

You can generate a report of the inventory details of the reagents displayed in the table (see "reagent or detection system details" on page 162). The report output can be controlled by the radio buttons described for "reagent inventory screen" on page 160. The generated report shows information for each of the visible reagents including the total volume remaining. If the total volume is less than the minimum stock volume (see "inventory tracking" on page 161) then it is flagged with "Low" in the report.

Click **Report**. The report is generated and displayed in a new window (see Figure 129). The top right of the reagent inventory report shows the information in the following table.

Field	Description
Facility	The name of the facility as entered in the Facility field of the Site Preferences dialog as described in "site preferences" on page 78
Subject	The displayed reagents as selected by the Show radio buttons

For each reagent listed in the table the body of the report displays:

- name
- total volume in stock (flagged if the volume is less than the minimum stock value)
- catalog number (for prefilled Vision Biosystems containers) or "open" (for open containers)
- type
- supplier
- UPI
- lot number
- date of expiry
- date when registered
- date when first used
- date when last used
- volume remaining

Click **the print icon** to obtain a copy of the report using the selected printer as described in "report printer configuration" on page 79.

Facility: Vision BioSystems

Subject: All preferred in stock reagents

Inventory details

***Anti-Fluorescein Antibody** **Vol. (mL)** 74.669

Open **Type** Ancillary **Supplier** Vision BioSystems

UPI	Lot No	Expiry	Registered	First used	Last used	Vol. (mL)
00010527		9/09/2009	21/03/2006	21/03/2006	23/03/2006	30.0
00010717		9/09/2009	21/03/2006	21/03/2006	24/03/2006	16.8
00018056		9/09/2009	21/03/2006	21/03/2006	24/03/2006	27.9

***Bond DAB Enhancer** **Vol. (mL)** 30

Open **Type** Ancillary **Supplier** Vision BioSystems

UPI	Lot No	Expiry	Registered	First used	Last used	Vol. (mL)
00006738		9/09/2009	21/03/2006	21/03/2006	23/03/2006	30.0

***CD10 (56C6)** **Vol. (mL)** 35.217

Open **Type** Primary **Supplier** Vision BioSystems

UPI	Lot No	Expiry	Registered	First used	Last used	Vol. (mL)
00010977		9/09/2009	21/03/2006	21/03/2006	24/03/2006	25.6
00011015		1/12/2009	16/08/2006	17/08/2006	17/08/2006	9.6

***CD20 (MJ1)** **Vol. (mL)** 86.05

Open **Type** Primary **Supplier** Vision BioSystems

UPI	Lot No	Expiry	Registered	First used	Last used	Vol. (mL)
00009780		9/09/2009	21/03/2006	21/03/2006	22/03/2006	30.0
00010989		9/09/2009	21/03/2006	21/03/2006	23/03/2006	30.0
00026592		9/09/2009	21/03/2006	21/03/2006	24/03/2006	26.0

***CD3 (LN10)** **Vol. (mL)** 30

Open **Type** Primary **Supplier** Vision BioSystems

UPI	Lot No	Expiry	Registered	First used	Last used	Vol. (mL)
00021301		9/09/2009	21/03/2006	21/03/2006	23/03/2006	30.0

***CMV Probe** **Vol. (mL)** 53.895

Open **Type** Probe **Supplier** Vision BioSystems

UPI	Lot No	Expiry	Registered	First used	Last used	Vol. (mL)
00021298		9/09/2009	21/03/2006	21/03/2006	24/03/2006	24.2
00021299		9/09/2009	21/03/2006	21/03/2006	22/03/2006	29.7

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Figure 129: Reagent inventory report

9.3.5 reagent usage report

The reagent usage report shows the quantity of reagent used and how many slides were processed with this reagent within a defined period. The information is itemized for individual containers as well as showing reagent totals.

The report covers all reagents used in the defined period, irrespective of the reagents currently displayed in the Reagent inventory screen. Detection system usage is not included.

Click **Reagent usage** to open a date selection dialog where you must set the period that you want the report to cover. Set *From* and *To* dates and times (see "using the date & time selector" on page 174), and then click **Generate**. The report is generated and displayed in a new window (see Figure 130).

The top right of the reagent usage report shows the information in the following table.

Field	Description
Facility	The name of the facility as entered in the Facility field of the Site Preferences dialog as described in "site preferences" on page 78
Time period	The "from" and "to" dates for the period that the report covers

For each reagent used in the period the report displays:

- Name (the reagent's abbreviated name);
- UPI of each container used;
- Lot number of each container used;
- Expiry date of each container used;
- Number of slides processed, both per container and the total for the reagent;
- Volume of reagent used in the period, both per container and the total for the reagent.

Click **the print icon** to obtain a copy of the report using the selected printer as described in "report printer configuration" on page 79.

Facility: Vision BioSystems
Time period: 11/08/2005...17/08/2006

Reagent usage

Name	UPI	Lot N°	Expiry Date	N° of slides processed	Volume used (mL)
***antiFITC**					
	00010527		9/09/2009	58	8.7
	00010717		9/09/2009	154	23.1
	00018056		9/09/2009	68	10.2
				280	**42**
***CD10**					
	00010977		9/09/2009	96	14.4
				96	**14.4**
***CD20**					
	00009780		9/09/2009	65	9.7
	00010989		9/09/2009	38	5.7
	00026592		9/09/2009	93	13.9
				196	**29.4**
***CD3**					
	00021301		9/09/2009	30	4.5
				30	**4.5**
***CMVpb**					
	00021298		9/09/2009	68	20.4
	00021299		9/09/2009	38	11.4
				106	**31.8**
***DABEnh**					
	00006738		9/09/2009	39	5.8
				39	**5.8**
***Enzyme1**					

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Figure 130: Reagent usage report

9.4 reagent panels screen

A panel is a user-defined set of antibodies. You can use panels to quickly add a number of slides onto the system.

To display the Reagent panels screen, click the reagent screen icon from the function bar, then click the Panels tab.

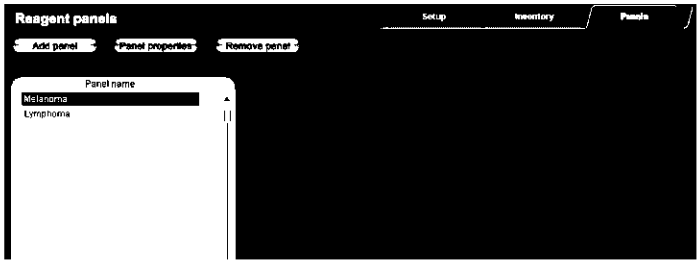


Figure 131: Reagent panels screen

9.4.1 defining a panel

To define a panel, do the following:

1. Click **Add panel**.
   The software will display the Reagent panel properties dialog.

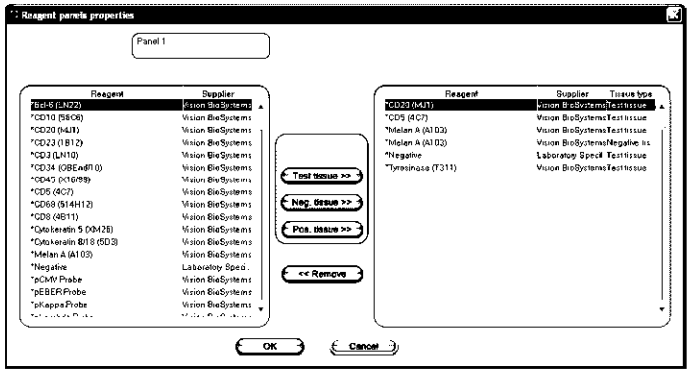


Figure 132: The Reagent panel properties dialog

   The table on the right of the Reagent panel properties dialog lists the contents of the panel, and the table on the left lists all of the available markers.

2. Enter a name for the panel in the *Panel name:* field at the top left of the dialog.
   You cannot save a panel without a name.

3. To add a marker to the panel, select an item on the list of available antibodies or probes in the table at the left, then click **Test tissue >>**.

   To add a positive tissue control, click on the marker then click **Pos. tissue >>**.
   To add a negative tissue control, click on the marker then click **Neg. tissue >>**.

4. To remove an item from the panel, select it in the table on the right and click **<< Remove**.

5. When the panel is correct, click **OK** to save the details.
   If you do not want to save the panel, click **Cancel**.

9.4.2 viewing or editing panel details

To view the details of a panel, select it in the table on the Reagent panels screen, then click **Panel properties**.
The software displays the Reagent Panel Properties dialog as described in "defining a panel" on page 170. To change the properties of the panel, add or remove primaries or probes as described there.

9.4.3 removing a panel

To remove a panel from the system, select it in the table on the Reagent panels screen, then click **Remove panel**. You will be asked to confirm the removal.

Remove panels with care.
You cannot recover details of deleted panels.

10

slide history

The Slide history screen displays details of slides that are scheduled, currently running, or have been run, on the Bond™ system. Slides are transferred to the Slide history screen from the Slide setup screen when they are first scheduled at the time a run is started.

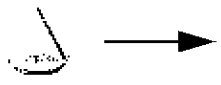
Batches that were scheduled but stopped before processing started (by unlocking the tray), have their individual slide records removed from the history list and replaced with a single row for the entire batch, showing status "Rejected". Run events and Batch details reports can be generated for these batches.

The history screen allows you to:

- View slide properties for individual slides.
  Refer to "slide properties, slide rerun and scoring" on page 175
- Create reports for run events for the batch of which a slide was a part.
  Refer to "run events report" on page 178
- Create batch detail reports for the batch of which a slide was a part.
  Refer to "batch details report" on page 180
- Create case detail reports for the case of which a slide was a part.
  Refer to "case report" on page 182
- Create slide summary reports that show the number of slides started in a selected date range.
  Refer to "slides summary report" on page 185
- Export all slide details in a format that can be easily manipulated using third-party software.
  Refer to "export data" on page 187

You can also see a Service events report for a batch, however this feature is designed for use by service personnel only (see "service reporting" on page 188) and is not described here.

To see slide history details or to generate run events, batch, case, or service reports, select the History icon from the Function bar. The Slide tab that shows the slide history is active by default, otherwise click to make it active.



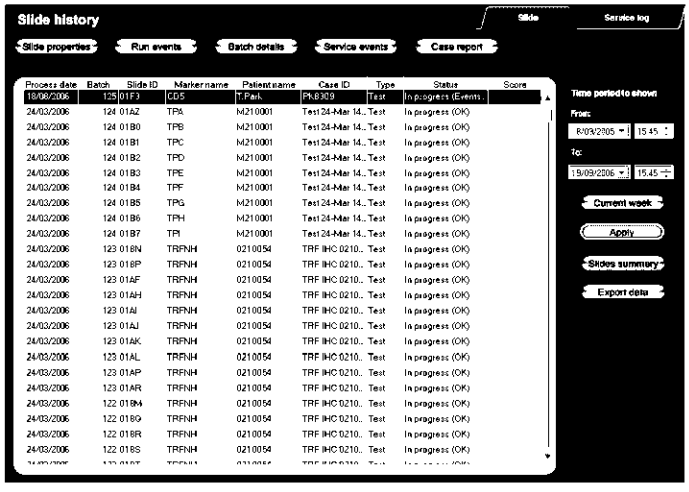


Figure 133: Select the History icon to display the Slide history screen

The table in the Slide history screen is the *Slide history list*. This will display the slides run in the period defined in the controls on the right (see "defining a time period" on page 174).

Manually entered slides are highlighted yellow in the list. Slides from an LIS system (for users with LIS-ip installed) have a light yellow background.

Each slide has the following values reported in the list:

- Process date (the date slide processing started)
- Batch number
- Slide ID
- Marker name
- Patient name
- Case ID
- Type (test, or positive or negative control)
- Status (in progress or done, and whether any unexpected events were noted; also possibly "Rejected" for batches that were stopped before processing began)
- Score (see "scoring slides" on page 177)

If the status is "Done (Events noted)", inspect the run events report to determine whether the unexpected events may have affected the staining. Unexpected events are displayed in bold text.

To view information about a slide, select it in the list, then click one of the buttons above the list. For more information on each of the options, see the following sections.

10.1 defining a time period

The Slide history screen has a date and time selector on the right (see Figure 134). Use this to specify the screen's reporting period; only slides processed within the period are displayed.

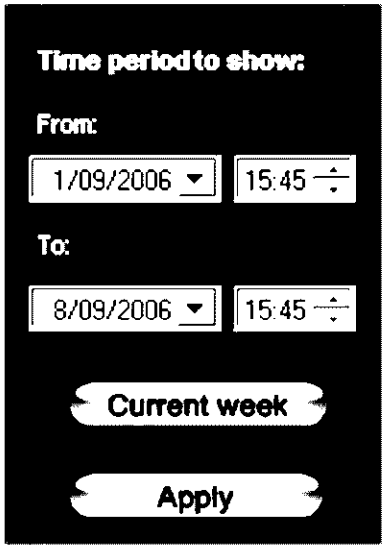


Figure 134: Date and time selector (initial display)

Set "from" and "to" dates and, if required, times, to define the time period to show. Then click **Apply** to display the slides.

When the date and time selector first opens the *To* field is set to the current date and time, and the From field to exactly one week prior. If you change settings you can return to this configuration with **Current week**.

using the date & time selector

To set day:

- click the drop-down arrow in the date field to open a calendar of the currently selected month, and click the day, or to select the current day click the red circle at the bottom of the calendar, or;
- select the day in the date field, then type in the required day or use the keyboard up and down arrow keys to step through the days one at a time.

To set month:

- click the drop-down arrow in the date field to open the calendar, then click the left or right arrows in the calendar title bar to scroll through the months, or click on the month name to open a list to select from, or;
- select the month in the date field, then type in the required month or use the keyboard up and down arrow keys to step through the months one at a time.

To set year:

- click the drop-down arrow in the date field to open the calendar, then click on the year in the calendar title bar to turn it into a spin box where you can select the year, or;
- select the year in the date field, then type in the required year or use the keyboard up and down arrow keys.

To set time:

- use the up and down spin arrows in the time field to change the time in 15 minute increments, or;
- set a new hour value by selecting the hour and then type in the required hour (24-hour clock) or use the keyboard up and down arrow keys to step through the hours one at a time, or;
- select the minutes and type in the required minutes value or use the keyboard up and down arrow keys to step through the minutes in 15 minute steps.

10.2 slide properties, slide rerun and scoring

To view the properties of a slide in the Slide history list, select the slide then click **Slide properties**. This will display the Slide properties dialog (Figure 135). This is the same as the Add slide dialog discussed in "creating a slide" on page 126, except the dialog now includes a "Scores" tab, and has different command buttons.

For Bond LIS-ip systems there may also be an LIS tab (see "LIS slide properties" on page 194).

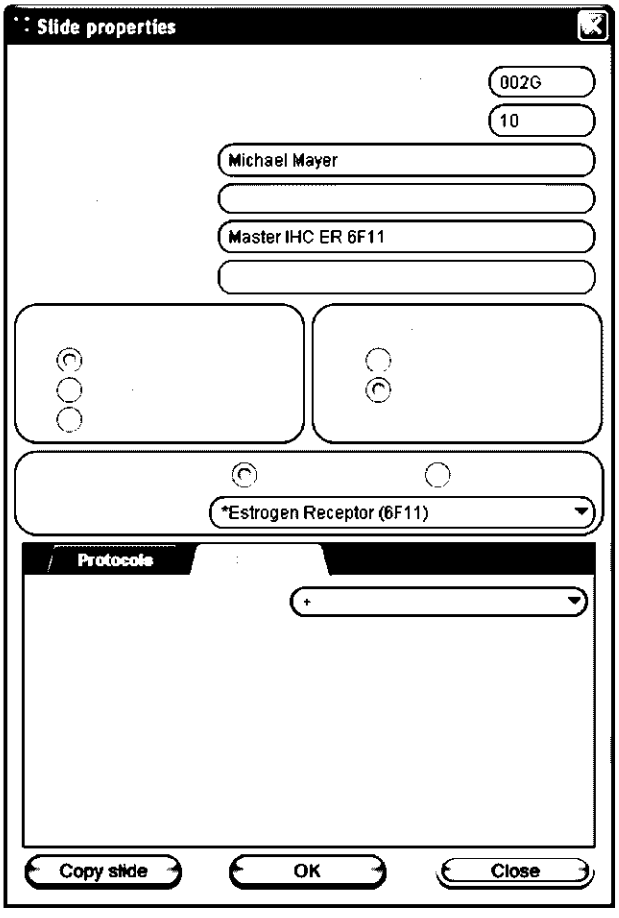


Figure 135: Slide properties dialog, including Scores tab, for slides that have been processed or for which processing has begun

You cannot edit any of the patient or test details in the Slide properties dialog when it is opened from the Slide history screen (since the slide has been, or is being, processed) but you can add comments in the *Comments:* field, rerun a slide or score a slide.

Note that you can open the Slide properties dialog for processed slides from the Item ID menu as well (see "ad hoc slide identification" on page 129).

10.2.1 rerunning slides

If the slide does not conform to requirements, then it may be flagged to be rerun. Use the following procedure to initiate a slide rerun from the "Slide properties" dialog:

1. Click **Copy slide** (you may be prompted to save the slide's details at this point, the usual response would be "Yes"). The protocol fields are now editable.
2. Make any required changes. Click **Add slide** to add the slide to the Slide setup screen (see "slide setup screen" on page 119).

   A dialog opens for you to confirm case details. You can proceed or cancel.
3. The slide properties dialog remains open to allow you, for example, to add any controls (Positive and Negative). You must click **Add slide** to add each slide to the Slide setup screen.
4. Click **Close** to return to Slide history screen.
5. Run the newly created slides in the normal manner.

10.2.2 scoring slides

For slides that have already been processed the "Slide properties" dialog has an additional *Score:* drop-down list that allows you to select a score for the slide.

To score a slide select the *Scores* tab at the bottom of the dialog (see Figure 135) and select the required score from the *Score:* drop-down list. Click **OK** to save the change. The operator's name (taken from the system logon) and time and date are saved with the score.

The scoring system can be configured from the options table (refer to "options table" on page 82). The following table lists the score option values.

Section	Key	Value
ScoreSystem	Score x (where x is a number from 0 to 9)	The desired score character or text

Up to 10 score values can be set for inclusion in the drop-down list. Any standard character (or combination of characters) can be used for slide scoring with typical systems using either a numerical rating (0,1,2 3 etc.) or an alphabetized system (A, B, C etc.). Slide scores may also consist of multiple characters (e.g. A1, B2 or Good, OK, Fail etc.). The number of characters for each entry should be limited to 15 to ensure the score is displayed correctly on reports. Leaving a value field empty disables the associated score key.

10.3 run events report

This report shows the events for the batch the selected slide was run with. Click **Run events** to display a preview of the report. The report is displayed in a new window. Events that initiated a slide notification are displayed in bold type so they can be easily found.

PM serial N°: M210005
Processing Module: M210005
Tray: 1
Dispense volume: 150 µL
Start time: 20/04/2006 12:57 PM
Batch progress: Finished

Run events: Batch 1

Time	Event N°	Description	Parameter	Value	Parameter ID
1:16:42 PM	1006	Unexpected reagent level detected	Reagent name:	*DAB Part 3	2006
			Reagent UPI:	00011132	2025
			Detection system UPI:	00011072	2026
			Expected reagent volume:	2400	2034
			Detected reagent volume:	8588	2035
1:22:09 PM	1032	Reagent dispensed	Reagent name:	*Bond Wash Solution	2006
			150 µL dispense position		2506
			All slides		2030
1:22:59 PM	1032	Reagent dispensed	Reagent name:	*Bond Wash Solution	2006
			Open fill 150 µL		2501
			All slides		2030
1:23:34 PM	1032	Reagent dispensed	Reagent name:	*Bond Wash Solution	2006
			150 µL dispense position		2506
			All slides		2030
1:24:35 PM	1032	Reagent dispensed	Reagent name:	TestReagentC	2006
			Reagent UPI:	00009762	2025
			150 µL dispense position		2506
			All slides		2030
1:40:10 PM	1032	Reagent dispensed	Reagent name:	*Bond Wash Solution	2006
			150 µL dispense position		2506

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Figure 136: An example of a Run events report

The top right of the Run events report shows the information in the following table.

Field	Description
PM Serial No	The serial number of the Processing Module that ran the batch
Processing Module	The name of the Processing Module that ran the batch
Tray	The number of the Slide Staining Assembly that ran the batch
Dispense volume	The volume of reagent for each dispense
Start time	The date and time that the batch was started
Batch progress	Whether the batch is Finished or still Processing.

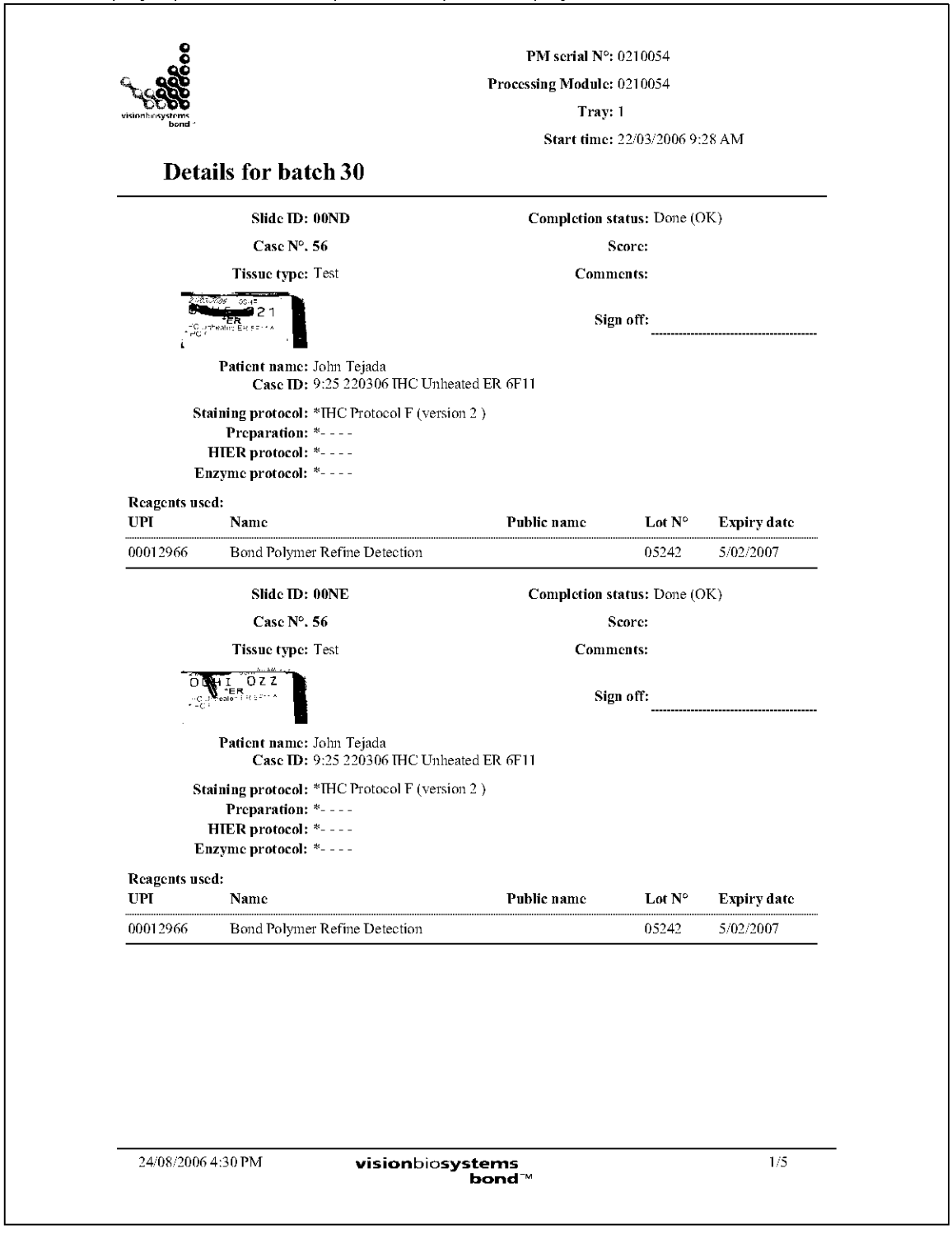
The body of the report displays the time, event number, and event description of the events for the batch. The event number is used by Vision BioSystems™ for error tracking if the need arises.

The footer of the report shows the time and date the report was printed, and the page number.

Click **the print icon**  to obtain a copy of the report using the selected printer as described in "report printer configuration" on page 79.

10.4 batch details report

This report shows the details of each slide in the same batch as the currently selected slide. Click **Batch details** to display a preview of the report. The report is displayed in a new window.



PM serial N°: 0210054
Processing Module: 0210054
Tray: 1
Start time: 22/03/2006 9:28 AM

Details for batch 30

Slide ID: 00ND **Completion status:** Done (OK)
Case N°. 56 **Score:**
Tissue type: Test **Comments:**
Sign off: .....

Patient name: John Tejada
Case ID: 9:25 220306 IHC Unheated ER 6F11

Staining protocol: *IHC Protocol F (version 2)
Preparation: *- - - -
HIER protocol: *- - - -
Enzyme protocol: *- - - -

Reagents used:

UPI	Name	Public name	Lot N°	Expiry date
00012966	Bond Polymer Refine Detection		05242	5/02/2007

Slide ID: 00NE **Completion status:** Done (OK)
Case N°. 56 **Score:**
Tissue type: Test **Comments:**
Sign off: .....

Patient name: John Tejada
Case ID: 9:25 220306 IHC Unheated ER 6F11

Staining protocol: *IHC Protocol F (version 2)
Preparation: *- - - -
HIER protocol: *- - - -
Enzyme protocol: *- - - -

Reagents used:

UPI	Name	Public name	Lot N°	Expiry date
00012966	Bond Polymer Refine Detection		05242	5/02/2007

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Figure 137: An example of a Batch details report

The top right of the report shows the information in the following table.

Field	Description
PM serial N°	The serial number of the Processing Module that ran the batch
Processing Module	The name of the Processing Module
Tray	The number of the Slide Staining Assembly that ran the batch
Start time	The date and time that the batch was started

For each slide in the batch the body of the report shows an image of the slide label and the following information.

Field	Description
Slide ID	The Bond system assigns a unique identifier to each slide
Case N°	A unique case identifier generated by the Bond System
Tissue type	Test tissue, positive control tissue, or negative control tissue
Patient name	Identification of the patient
Case ID	Case identification entered during slide setup
Staining protocol	The staining protocol used
Preparation	The preparation protocol used (if any)
HIER protocol	HIER protocol used (if any)
Enzyme protocol	Enzyme retrieval protocol used (if any)
Denaturation	For ISH only, denaturation protocol used (if any)
Hybridization	For ISH only, hybridization protocol used (if any)
LIS reference [2 to 7]	Additional LIS reference information for systems with LIS-ip installed *(see "LIS slide properties" on page 194)*
Completion status	Indicates whether the slide is being processed, completed, or has been scored. Also whether any error conditions were noted.
Score	A score can be entered into a slide's properties after the slide has been processed (see "scoring slides" on page 177)
Comments	Comments can be entered into a slide's properties at any time
Sign off:	Sign off is a reserved space on the printed paper report where a supervisor can sign off the Score and Comments
Reagents used	
UPI	Unique Pack Identifier of every reagent used for this slide
Name	Name of every reagent used for this slide
Public name	Public name, for systems with LIS-ip installed
Lot N°	Lot number of every reagent used for this slide
Expiry Date	Expiry date of every reagent used for this slide

The footer of the report shows the time and date the report was printed, and the page number.

Click **the print icon** to obtain a copy of the report using the selected printer as described in "report printer configuration" on page 79.

10.5 case report

This report shows the details of each slide in the same case as the currently selected slide. If the case ID selected in the Slide history window has multiple case numbers, then a dialog is displayed listing all case numbers associated with this case ID.

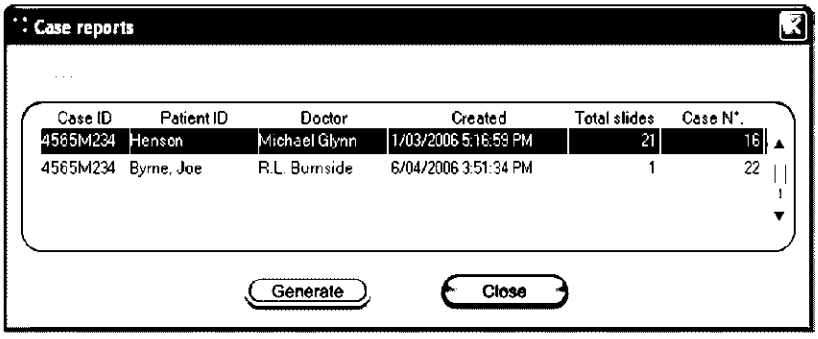


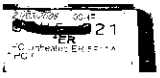
Figure 138: Duplicate case ID
with unique case numbers in right column

Select the required case number (first column from the right) and click **Generate** to display a preview of the report (see Figure 139). Otherwise click **Close** to return to the Slide history window.

Case ID: 9:25 220306 IHC Unheated ER 6F11
Patient name: John Tejada
Case comments:
Doctor: Rebecca Coates
Doctor comments:
Created: 22/03/2006 9:25 AM
Case N°: 56

Details for case 56

Slide ID: 00ND **Completion status:** Done (OK)
Batch: 30 **Score:**
Tissue type: Test **Comments:**



Sign off: ----------

Staining protocol: *IHC Protocol F (version2)
Preparation: *- - - -
HIER protocol: *- - - -
Enzyme protocol: *- - - -

Reagents used:

UPI	Name	Public name	Lot N°	Expiry date
00012966	Bond Polymer Refine Detection		05242	5/02/2007

Slide ID: 00NE **Completion status:** Done (OK)
Batch: 30 **Score:**
Tissue type: Test **Comments:**

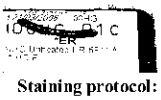
Sign off: ----------

Staining protocol: *IHC Protocol F (version2)
Preparation: *- - - -
HIER protocol: *- - - -
Enzyme protocol: *- - - -

Reagents used:

UPI	Name	Public name	Lot N°	Expiry date
00012966	Bond Polymer Refine Detection		05242	5/02/2007

Slide ID: 00NF **Completion status:** Done (OK)
Batch: 30 **Score:**
Tissue type: Test **Comments:**



Sign off: ----------

Staining protocol: *IHC Protocol F (version2)
Preparation: *- - - -
HIER protocol: *- - - -

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Figure 139: An example of a Case report

The top right of the case report shows the information in the following table.

Field	Description
Case ID	Case identification entered during slide setup
Patient name	Patient name
Case comments	Additional case information
Doctor	Name of the doctor or referring pathologist in charge of the patient
Doctor comments	Additional doctor information
Created	Date and time that the batch was started
Case N°	A unique case identifier generated by the Bond System

The body of the report shows the following information for each slide in the case.

Field	Description
Slide ID	The Bond system assigns a unique identifier to each slide
Batch	The number of the batch
Tissue type	Test tissue, positive control tissue, or negative control tissue
Staining protocol	The staining protocol used
Preparation	The preparation protocol used (if any)
HIER protocol	HIER protocol used (if any)
Enzyme protocol	Enzyme retrieval protocol used (if any)
Denaturation	For ISH only, denaturation protocol used (if any)
Hybridization	For ISH only, hybridization protocol used (if any)
LIS reference (2 to 7)	Additional LIS reference information for systems with LIS-ip installed *(see "LIS slide properties" on page 194)*
Completion status	Indicates whether the slide is being processed, completed, or has been scored. Also whether any error conditions were noted.
Score	A score can be entered into a slide's properties after the slide has been processed (see "scoring slides" on page 177)
Comments	Comments can be entered into a slide's properties at any time
Sign off:	Sign off is a reserved space on the printed paper report where a supervisor can sign off the Score and Comments
Reagents used	
UPI	Unique Pack Identifier of every reagent used for this slide
Name	Name of every reagent used for this slide
Public name	Public name, for systems with LIS-ip installed
Lot N°	Lot number of every reagent used for this slide
Expiry Date	Expiry date of every reagent used for this slide

The footer of the report shows the time and date the report was printed, and the page number.

Click **the print icon** to obtain a copy of the report using the selected printer as described in "report printer configuration" on page 79.

10.6 slides summary report

The slides summary report shows the number of slides for which processing was started within a stipulated period, or for the life of the system. You can configure the report to show the number of slides processed on the whole system, or on a particular Processing Module. The information is displayed in both tabular and graphical format as the number of slides processed per unit time, within the stipulated period.

To report the number of slides processed, click **Slides summary** to open the Slides summary dialog.

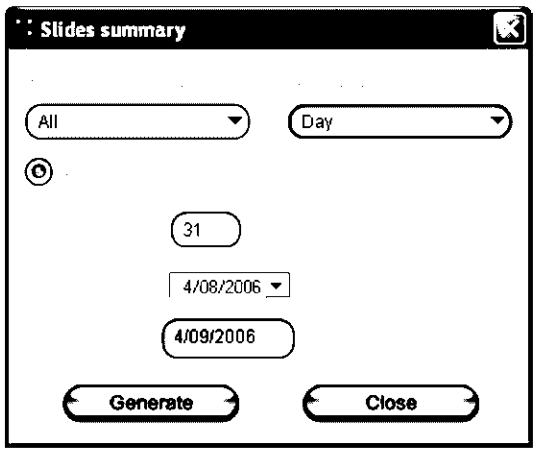


Figure 140: Slides summary dialog

Choose either a particular Processing Module by its name or "All PMs" (the whole system) from the *Processed on* drop-down list.

In the *Resolution* field select the time unit to be used to report the number of slides started, e.g. "Day" generates a report showing the number of slides started each day within the stipulated time period, while "Month" gives the number of slides started each month within the period.

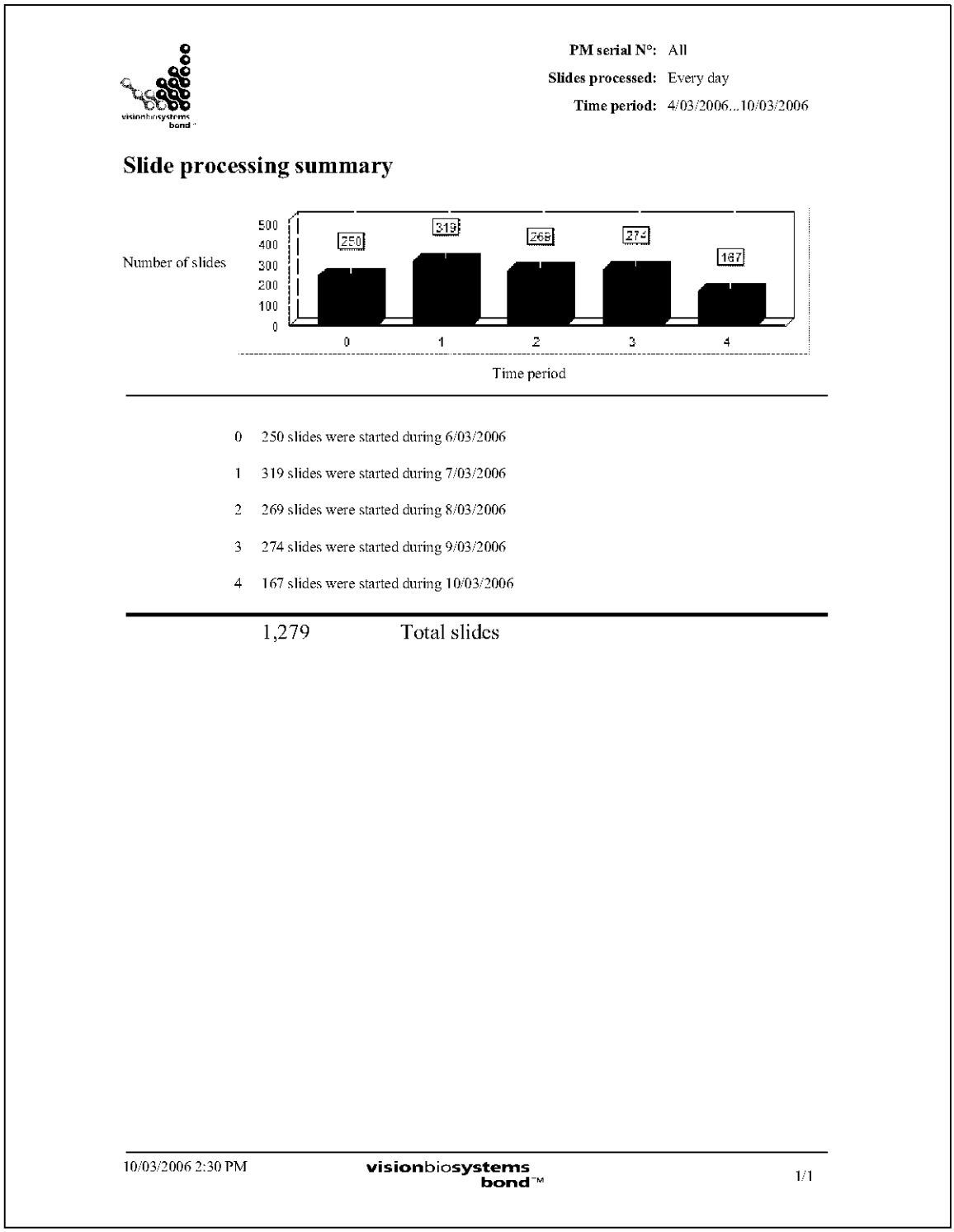
To have the report show the entire history of the selected Processing Modules deselect *Slides within time period*. To stipulate a specific period for the report to cover, select *Slides within time period* and define the period using the *Period* and *From* fields.

The period must be defined in the time units selected for the *Resolution* field. For example, if you want to report the number of slides processed per month in a year, set *Resolution* to "Month" and then define the one year period in months, i.e. type 12 into the *Period* field. Similarly, to show the number of slides processed per day for a month, set *Resolution* to "Day" and type 31 in the *Period* field.

Set the "from" and "to" dates for the defined period using the *From* field only—the *To* field shows the date determined by the *Period* and *From* settings. Make sure that you haven't inadvertently set the "to" date to the future.

Click **Generate** to preview the report (see Figure 141), or **Close** to exit the dialog.

Click **the print icon** to obtain a copy of the report using the selected printer as described in "report printer configuration" on page 79.



PM serial N°: All
Slides processed: Every day
Time period: 4/03/2006...10/03/2006

Slide processing summary

0	250 slides were started during 6/03/2006	
1	319 slides were started during 7/03/2006	
2	269 slides were started during 8/03/2006	
3	274 slides were started during 9/03/2006	
4	167 slides were started during 10/03/2006	
	1,279	Total slides

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Figure 141: An example of a Slides summary report

10.7 export data

Clicking **Export data** creates a file containing the details of all slides in the selected date range. The exported file is in the standard "comma separated values" (csv) file format and the file can be easily imported into third-party spreadsheet applications such as Microsoft Excel. Once imported into a spreadsheet, the data is presented in a format that allows (depending on spreadsheet functionality) sorting, searching and the creation of customized reports and graphs.

For each slide in the selected date range, the following information will be included in the exported file:

- Process time
- PM serial number
- Slide ID
- Marker name
- Case ID
- Score
- Doctor
- Dispense volume
- Preparation protocol name
- HIER protocol name
- Enzyme protocol name
- Denaturation protocol name
- Hybridization protocol name
- Staining protocol name
- Detection system name
- PM name
- Batch
- Marker UPI
- Patient name
- Type (Test, or positive or negative control)
- Scored by
- Status
- Comments
- Preparation protocol version
- HIER protocol version
- Enzyme protocol version
- Denaturation protocol version
- Hybridization protocol version
- Staining protocol version
- Detection system serial number

Use the following procedure to export slide details.

1. Select the required date range (refer to "defining a time period" on page 174).
2. Click **Export data.**
3. In the Windows "Save as" dialog set the following options:
   (i) In the *Save in:* field, select the directory where you wish to save the file.
   This may be the default directory "C:\Program Files\Vision BioSystems\Bond\SlideHistory", another directory on the host computer's hard drive, or an external device such as a USB key.
   (ii) In the *File name:* field, either leave the default name or type in a name you would like for this file.
   The default name includes the time period selected.

(iii) Leave the *Save as type:* field set to "CSV Files (*.csv).

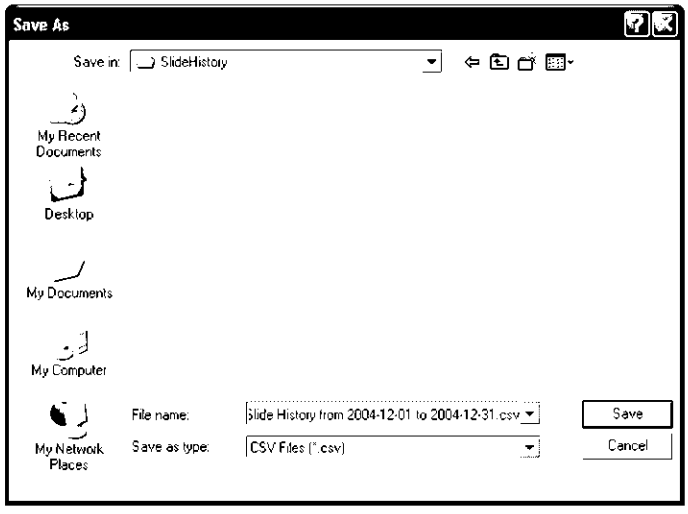


Figure 142: Save as dialog with default options

4. Once all options are set, click **Save** to save the file to the selected location.

The saved file can be opened in a standard spreadsheet program such as Microsoft Excel and manipulated according to the functions available in the application. When opening the file you may need to specify some file parameters. The file is in "csv" format, the parameters are as follows:

- The file type is **Delimited**
- The file origin is **Windows (ANSI)**
- The **Delimiter** or **Separator** is a **Comma**
- Use a **General** column format.

10.8 service reporting

The Service events report generated with **Service events** on the Slide tab, and the "Service log" tab are intended for use by, or under the direction of, Vision BioSystems service representatives. For this reason these screens are not discussed in this User manual.

11

LIS integration package

The optional Bond™ LIS integration package (LIS-ip) connects the Bond system to any compatible Laboratory Information System (LIS). The LIS-ip is highly configurable so it can work with many different LIS types and laboratory workflows. The main function of the LIS-ip is to pass information between the laboratory's LIS and the Bond system. Typically, the LIS feeds case and/or slide information to the Bond system and the Bond system returns processing status information to the LIS. The actual information shared differs between systems as does the method for providing slide labels and the data transfer method (some systems are automatic, some require a data request from the Bond system).

This chapter of the Bond user manual provides an overview of Bond LIS-ip operation. The LIS-ip implementation will be customized by an authorized Vision BioSystems™ representative and the LIS may need to be modified by the LIS vendor.
Vision BioSystems can arrange comprehensive site-specific training for each installation.

Refer to the following sections for Bond LIS-ip information:

- New terms relating to LIS-ip operation
  Refer to "LIS terminology" on page 190
- Details of additional software functions
  Refer to "additional software features" on page 190
- An overview of LIS connection and configuration
  Refer to "LIS connection and initialization" on page 195
- A description of LIS error indication and recovery
  Refer to "LIS errors" on page 195
- A reference list of cases and slides data
  Refer to "case and slide data" on page 196
- A reference to slide label requirements
  Refer to "slide labels" on page 199
- Workflow examples for a range of typical LIS implementations
  Refer to "working with an LIS" on page 201.

11.1 LIS terminology

A number of new terms are required to describe LIS functionality and to differentiate between normal Bond elements and LIS elements. These terms are described in the following list.

- LIS — Laboratory Information System; software that manages information related to a laboratory's work.
- LIS-ip — the Bond LIS integration package, an optional add-on that enables the Bond system to work with an LIS.
- Bond slide — a slide created using the Bond software (as per the standard Bond workflow).
- Bond case — a case created using the Bond software (as per the standard Bond workflow).
- LIS slide — a slide created by the LIS and sent to the Bond system for processing.
- LIS case — a case created by the LIS and sent to the Bond system.
- Bond slide label — a slide label printed by the Bond system for a Bond slide.
- LIS slide label — a slide label printed by the Bond system for an LIS slide.
- External slide label — a slide label not printed from the Bond system (possible sources include the LIS, a third-party application, or handwritten labels).
- Auto-ID slide label — a slide label that can be automatically recognized by the Bond system and matched to a pending test. These can be either Bond or LIS labels but must be printed from the Bond system.
- Assisted-ID slide label — any slide label that cannot be automatically recognized. Bond displays an image of each assisted-ID slide label to help the operator match each slide to a pending test. These labels can be created from any source (Bond, LIS, third-party, handwritten).
- Accession number — A common LIS term for a number or other ID that identifies a particular case. Accession number is equivalent to the Bond "Case ID".
- Patient data — Patient details that form a "Case" on the Bond system.
- Demographic data — A common LIS term for patient data or case data.
- Test data — The test details that form a slide for processing on Bond (i.e. includes the marker name, test type, etc.).

11.2 additional software features

LIS-enabled Bond systems have additional software features not found in the standard version. This section describes these additional functions.
Bond LIS-ip systems retain all the features and functions of standard Bond software.

Refer to the following sections for detailed information on each of the additional functions:

- "LIS panel" on page 191
- "LIS cases" on page 191
- "LIS slides" on page 192
- "LIS slide labels" on page 192
- "public marker names" on page 193
- "priority slides" on page 193
- "get LIS data" on page 193
- "LIS slide properties" on page 194

11.2.1 LIS panel

Figure 143: Truncated function bar image with LIS panel at the far right

Bond software with the LIS-ip includes the LIS panel at the far right of the standard function bar. This panel has the following functions:

- LIS connection status (refer to "LIS connection and initialization" on page 195)
- LIS error indication (refer to "LIS errors" on page 195)
- Get LIS data (refer to "get LIS data" on page 193).

11.2.2 LIS cases

Any case generated by the LIS is created in Bond as an LIS case. The following points describe the rules applying to LIS cases.

- LIS cases contain the same property fields as Bond cases but no information can be edited.
- The Bond system automatically allocates a unique Case number to every LIS case (in the same manner as Case numbers are allocated to Bond cases).
- The LIS accession number or case ID becomes the Case ID within Bond. Where the LIS case has the same accession number (Case ID) as an existing Bond case, a new LIS case is created with the same Case ID but a unique Case number.
- Copies of an LIS case made with the Bond software are created as Bond cases.
  These cases have the same properties as the original but a unique Case number.
  The case properties are editable.
  Any slides contained in the original case are recreated in the copy as Bond slides.
- Slides added to an LIS case using the Bond software are created as Bond slides.

11.2.3 LIS slides

Any slide initiated by the LIS is created in Bond as an LIS slide. LIS slides can be identified in the slide list by their label color: LIS-generated slides have a grey label while Bond slides have a white label.

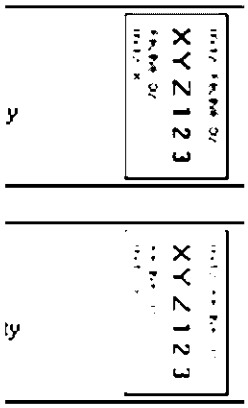


Figure 144: LIS slide (top) and Bond slide (bottom)

The following points describe the rules applying to LIS slides.

- Labels printed from Bond for LIS slides use the LIS slide label configuration.
  Refer to "LIS slide labels" on page 192.
- LIS slides properties include a *Public marker:* field in addition to all the property fields used for Bond slides.
  Refer to "public marker names" on page 193.
- LIS slides may also include additional LIS-specific fields.
  Refer to "LIS slide properties" on page 194.
- Slide properties originating from the LIS cannot be edited using the Bond software.
  Fixed properties always include the *Marker:* and *Public marker:* fields.
- When the Bond software is used to copy an LIS slide, the copy is created as a Bond slide.
  All fields become editable.
  All LIS-specific fields are removed.
  The slide label reverts to the Bond slide label configuration.

11.2.4 LIS slide labels

LIS slide labels printed from the Bond software can be configured to use a different layout to that used for Bond slides. Configure the LIS layout in the slide label editor opened from the "LIS slide labels..." command in the Configuration menu, Local submenu.

Bond automatically prints the correct label layout for each slide, i.e. even in a print run with mixed Bond and LIS slides, the appropriate label layout is used for each slide.

Note that the default LIS label layout is identical to the default Bond label layout.

See "slide label configuration" on page 67 for directions on label configuration.

11.2.5 public marker names

Public marker names (for primary antibodies and probes) provide the link between markers specified by an LIS and those registered on the Bond system. When an LIS specifies a marker for a test, the Bond system uses the reagent with the identical public marker for that test. The Bond system will reject an LIS-specified test if there is no public name corresponding to the LIS marker name.

Public markers are specified using the *Public name:* field in the "Edit reagent properties" dialog (refer to "reagent setup screen" on page 158). This field only becomes visible when the LIS-ip is installed).

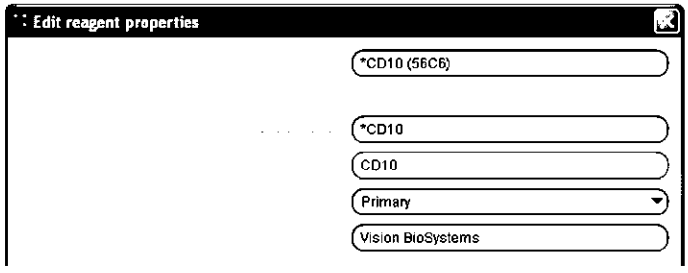


Figure 145: Reagent properties screen with "Public name:" field

Each public name must be unique. Public names can be swapped between Bond reagents at any time and when this occurs slides already created are not affected. The *Public name:* field can be edited for all markers including predefined Vision BioSystems markers.

11.2.6 priority slides

The LIS can specify priority slides that require urgent processing. Any case that includes a priority slide is highlighted red in the case list (refer to "slide setup screen" on page 119).

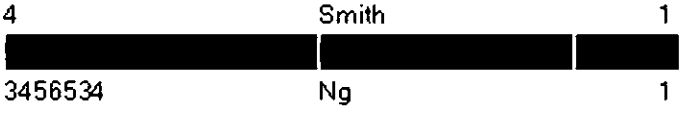


Figure 146: The middle case has one or more priority slides so is highlighted red

11.2.7 get LIS data

The LIS-ip may be configured so that the Bond system can request data from the LIS (rather than the LIS automatically sending the data). When the option is active, the "Get LIS data" symbol appears on the LIS panel (refer to "LIS panel" on page 191).

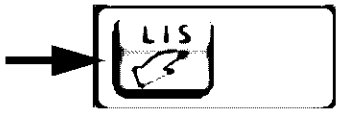


Figure 147: LIS panel with Get LIS data function active

Use the following instructions to request LIS data:

1. Click the "Get LIS data" symbol on the LIS panel.
2. Enter the accession number (or equivalent) in the "LIS data request" dialog.

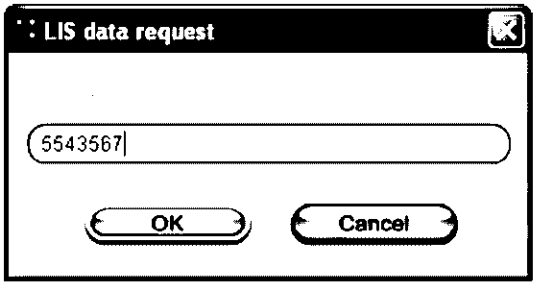


Figure 148: Entering the accession number

3. Click **OK** to request case information based on the entered accession number.
4. The Bond system will load the case and (depending on configuration) slide details as they are sent from the LIS.

The Get LIS data function is enabled from the Options table (see "options table" on page 82). The option settings are shown below.

Section	Key	Value
LIS	GetDataEnabled	• 0 — Get LIS data disabled • 1 — Get LIS data enabled

11.2.8 LIS slide properties

In addition to the standard slide properties, Bond LIS-ip has seven configurable data fields that can be set up to display selected information from the LIS. Basic connectivity is set up by the Vision BioSystems service representative during installation, however once this is in place users can choose to display the fields or not, and can set the name of each field, from the system options (see below).

The fields are displayed on a special "LIS" tab in the Slide properties dialog, and can also be printed on slide labels (see "slide label configuration" on page 67). They are for reporting purposes only and have no effect on Bond processing.

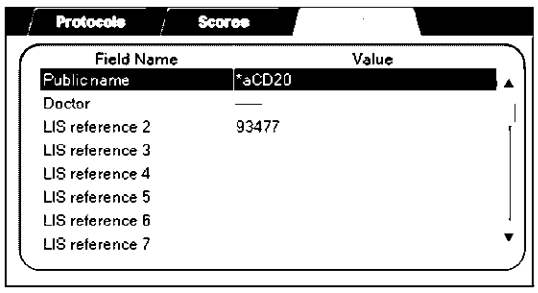


Figure 149: Additional LIS information in the "Slide properties" dialog

The seven LIS data fields are configured in the "Options table" (see "options table" on page 82 for directions in setting options).

The *Section*, *Key* and *Value* entries that control the fields are shown below. The "*x*" in the key names is the field number, ranging from 2 to 8.

Section	Key	Value
LISReferences	LISRef*x*Name — the field name	Enter the field name that will appear on the LIS tab in the Slide properties dialog.
	LISRef*x*Visible — field visibility	• 0 — The field is hidden • 1 — The field is visible

11.3 LIS connection and initialization

Each Bond LIS-ip module must be installed by an authorized Vision BioSystems representative who will customize the operation in accordance with individual laboratory requirements. Once the LIS module is installed, a new icon appears on the Bond software's function bar to indicate LIS connection status (Figure 150 and Figure 151)

Figure 150: LIS not connected

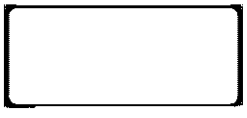


Figure 151: LIS connected

The LIS-ip can be turned on or off by entering or removing a password from the options table (refer to "options table" on page 82). The password is supplied by Vision BioSystems and is encoded so it will only work for the specific system for which it was created. The LIS-ip option details are shown below.

Section	Key	Value	Editable
Options	LIS interface	• Blank — LIS-ip disabled • Password entered — LIS-ip enabled	Yes

11.4 LIS errors

Bond indicates any LIS connection or data errors by displaying the notification icon on the LIS panel (refer to "LIS panel" on page 191). Errors are also added to the service log (refer to "service reporting" on page 188). To find error details, right-click the notification symbol and select "Show LIS report". This clears the notification and opens the LIS report. This report displays a list of errors and indicates any slides or cases that were not successfully transferred between the LIS and the Bond system. The reason for the error is also listed. Typical LIS errors include missing data, data conflicts (i.e. the same

accession number used for different cases), or instances where the public marker is not registered on the Bond system (refer to "public marker names" on page 193).

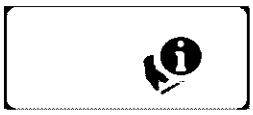
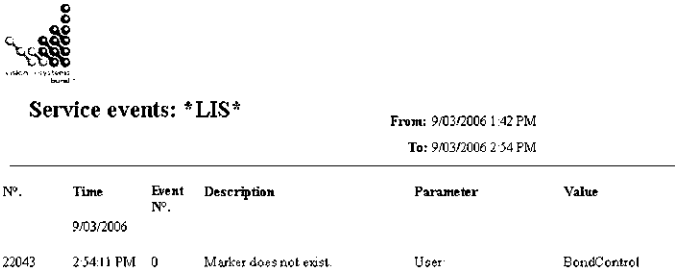


Figure 152: LIS error icon

Depending on the LIS configuration, it may be possible to correct the errors and resubmit the case or slide. Where the LIS is unable to re-send the information, the case or slides can be created directly using the Bond software.



Service events: *LIS*

From: 9/03/2006 1:42 PM
To: 9/03/2006 2:54 PM

Nº.	Time	Event Nº.	Description	Parameter	Value
	9/03/2006				
22043	2:54:11 PM	0	Marker does not exist.	User	BondControl

Figure 153: LIS report detail

11.5 case and slide data

The Bond system requires case (demographic) data and slide (test) data before it can process a slide. This data can be supplied by any combination of LIS, Bond user entry and Bond automatic generation. Any information entered using the Bond system can be edited prior to a slide actually running whilst LIS-generated information is locked and cannot be altered once sent from the LIS.

The information required to create a Bond case and corresponding slides is detailed in "case information" on page 197 and "slide information" on page 198. Note that mandatory values must be provided and can be from any of the three sources (LIS, Bond user or Bond automatic generation). Optional values can be omitted.

The information source along with slide labelling options and status reporting options determine the actual Bond workflow. Whilst each Bond LIS-ip installation is highly customized for site-specific operation, four basic workflow scenarios are described in "working with an LIS" on page 201.

Bond LIS-ip is also able to report slide information to the LIS. Depending on the system's configuration, the LIS-ip can provide slide status, slide scoring and other information. Refer to "slide reporting" on page 199 for a list of slide data that can be reported to the LIS.

11.5.1 case information

The following table documents the information associated with a Bond case.

Bond field name	Description	Corresponding LIS data (typical)	Possible data source	Mandatory or Optional
• Case ID	• A number or name identifying the case	• Accession number • Placer Order Number	• Bond user • LIS • Automatic generation Refer to "daily case option" on page 135	• Optional
• Patient name	• The name of the patient	• Patient name • Lab assigned ID (labAssId)	• Bond user • LIS	• Optional
• Doctor	• Identifies the referring physician	• Doctor name and/or identification number • Attending doctor • Ordering physician	• Bond user • LIS	• Optional
• Case Nº	• A unique number automatically assigned by the Bond system to ensure all cases have a unique identifier	• Not applicable	• Bond automatic generation	• Mandatory
• Dispense volume (Default)	• Default dispense volume for slides in this case (100 µL or 150 µL)	• Not applicable	• Bond user • Automatic generation using system default value	• Mandatory (uses "Site preferences" value if not specified)
• Preparation (Default)	• Default preparation protocol for slides in this case	• Not applicable	• Bond user • Automatic generation using system default value	• Mandatory (uses "Site preferences" value if not specified)

11.5.2 slide information

The following table documents the information associated with a Bond slide.

Bond field name	Description	Corresponding LIS data (typical)	Possible data source	Mandatory or Optional
• Tissue type	• Test or control (+ or -)	• Tissue type	• Bond user (optional) • LIS • Automatic generation with "Test" selected if no value chosen	• Mandatory (Defaults to "Test" if not specified)
• Dispense volume (Actual)	• Dispense volume option (100 µL or 150 µL)	• Not applicable	• Bond user • Automatic generation using case default value	• Mandatory (Uses case default if not specified)
• Marker	• Primary antibody (IHC) or Probe (ISH)	• Primary antibody (IHC), Probe (ISH), or Marker (either)	• Bond user • Automatically generated Uses reagent corresponding to the LIS public marker	• Mandatory
• Public marker	• Public marker name to match LIS marker to Bond reagent	• Universal test ID	• LIS	• Mandatory for LIS slides • Not applicable to Bond slides
• Protocols: • IHC and ISH Staining Preparation HIER Enzyme • ISH only Denaturation Hybridization	• The various protocols to run on a particular slide	• Not applicable	• Bond user • Automatic generation using reagent and case default values	• Mandatory (Uses reagent and case defaults if not specified)
• Comments	• Any comment or instruction relating to the slide	• Comment	• Bond user • LIS	• Optional

11.5.3 slide reporting

The Bond LIS-ip is able to report slide status and other information to the LIS. The actual information reported (if any) depends on the LIS-ip configuration. Bond LIS-ip can report the following information:

- Slide created — a slide has been created within the Bond software for the specified test
- Slide printed — a label has been printed for the specified slide
- Slide in progress — the specified slide is being processed
- Slide scored — reports the score for the specified slide
  Refer to "slide properties, slide rerun and scoring" on page 175
- Slide deleted — the specified slide has been deleted from the Bond system.

11.6 slide labels

Each physical slide requires an identification label so that it can be matched to the correct case and test information. The slide labels can be from an external source (LIS, other system, handwritten) or they can be printed directly from Bond.

The Bond software allows configuration of two distinct slide labels — one for Bond slides and one for LIS slides. Bond automatically prints the correct label layout for each slide (see "slide label configuration" on page 67), even if printing labels for a mixture of Bond and LIS slides in the same print batch.

Depending on the label configuration, slide labels printed by Bond may be automatically recognized after being imaged in the Processing Module (auto-ID labels) or they may require manual selection (assisted-ID labels). Externally sourced slide labels are always assisted-ID labels.

The following sections describe each of the five possible label combinations.

11.6.1 bond slide labels — auto-ID

- Labels printed from Bond.
- The case can be either a Bond or LIS case.
- The slides must be Bond slides.
- The Bond system will automatically recognize and identify slides with these labels (refer to "automatic slide identification" on page 108).

11.6.2 bond slide labels — assisted-ID

- Labels printed from Bond.
- The case can be either a Bond or LIS case.
- The slides must be Bond slides.
- The Bond system presents the operator with an image of the slide label so it can be manually matched to a Bond slide (refer to "assisted slide identification" on page 109).

11.6.3 LIS slide labels — auto-ID

- Labels printed from Bond.
- The case must be an LIS case.
- The slides must be an LIS slides.
- The Bond system will automatically recognize and identify slides with these labels (refer to "automatic slide identification" on page 108).

11.6.4 LIS slide labels — assisted-ID

- Labels printed from Bond.
- The case must be an LIS case.
- The slides must be an LIS slides.
- The Bond system presents the operator with an image of the slide label so it can be manually matched to a Bond slide (refer to "assisted slide identification" on page 109).

11.6.5 external slide labels

- Labels created from an external source (e.g. the LIS, a third-party system, handwritten).
- The case can be either a Bond or an LIS case.
- The slides can be either Bond or LIS slides.
- The Bond system presents the operator with an image of the slide label so it can be manually matched to a Bond slide (refer to "assisted slide identification" on page 109).

According to the standard Bond workflow, Bond must print a label for a slide before the slide can be recognized and processed by the Bond system. To allow externally labelled slides the system must be reconfigured so that Bond slide label printing is not necessary. This option is configured from the options table (refer to "options table" on page 82). There are separate option values for Bond and LIS slides as shown below.

Section	Key	Value	Function
IdentificationOptions	ForceNativePrinting	ForceNativePrintingOn	Bond must print a label before a Bond slide can run
		ForceNativePrintingOff	Bond slides can run without Bond printing a label
IdentificationOptions	ForceLISPrinting	ForceLISPrintingAuto	Bond prints LIS labels on reception
		ForceLISPrintingManual	LIS labels must be printed manually
		ForceLISPrintingOff	LIS slides can run without Bond printing a label

11.7 working with an LIS

While each LIS-ip implementation is highly customized, it is still helpful to provide some general descriptions of Bond LIS-ip workflows based on the major LIS-ip options. The following sections provide workflow overviews for some typical LIS-ip scenarios. Other workflows are also possible. Comprehensive site-specific training is provided for each installation.

11.7.1 LIS supplies demographic data only

Two scenarios are presented in this section for configurations where the LIS supplies demographic data only. The two scenarios illustrate the workflows needed for each of the data transfer methods (LIS submission and Bond request).

scenario 1 — LIS submits data

Patient demographics (case)	LIS
Tests (slides)	Bond
Slide labels	Bond, auto-ID
Data transfer method	LIS submission

The following is a workflow outline for a Bond LIS-ip configuration with LIS demographic data, LIS data submission, Bond test data and auto-ID Bond slide labels.

1. Mandatory patient details are entered into the LIS.
   Refer to "case information" on page 197.
2. LIS submits patient details to the Bond system.
3. The Bond software creates a case with the LIS-submitted details.
   Refer to "working with cases" on page 121.
4. The required slides are added to the case using the Bond software.
   Refer to "working with slides" on page 125.
5. The Bond operator prints slide labels and applies them to the appropriate slides.
   Refer to "slide labelling" on page 129.
6. The slides are loaded onto a Bond Processing Module and are automatically recognized by the Bond system.
   Refer to "automatic slide identification" on page 108.
7. The Bond operator starts the batch and the slides are processed.
   Refer to "running a protocol" on page 98.

scenario 2 — bond requests data

Patient demographics (case)	LIS
Tests (slides)	Bond
Slide labels	Bond, auto-ID
Data transfer method	Bond request

The following is a workflow outline for a Bond LIS-ip configuration with LIS demographic data, Bond data request, Bond test data and auto-ID Bond slide labels.

1. Mandatory patient details are entered into the LIS.
   Refer to "case information" on page 197.
2. The Bond operator requests LIS data using the **Get LIS data** button.
   Refer to "get LIS data" on page 193.
3. The LIS sends the demographic data for the accession number requested by the Bond system.
4. The Bond software creates a case with the LIS-submitted details.
   Refer to "working with cases" on page 121.
5. The required slides are added to the case using the Bond software.
   Refer to "working with slides" on page 125.
6. The Bond operator prints slide labels and applies them to the appropriate slides.
   Refer to "slide labelling" on page 129.
7. The slides are loaded onto a Bond Processing Module and are automatically recognized by the Bond system.
   Refer to "automatic slide identification" on page 108.
8. The Bond operator starts the batch and the slides are processed.
   Refer to "running a protocol" on page 98.

11.7.2 LIS supplies demographic and test data

Two scenarios are presented in this section for configurations where the LIS supplies both demographic and test data. The two scenarios illustrate the workflows needed for different slide label options.

scenario 3 — auto-ID LIS slide labels

Patient demographics (case)	LIS
Tests (slides)	LIS
Slide labels	LIS, auto-ID
Data transfer method	LIS submission

The following is a workflow outline for a Bond LIS-ip configuration with LIS demographic data, LIS test data, auto-ID LIS slide labels and LIS data submission.

1. Mandatory demographic details are entered into the LIS.
   Refer to "case information" on page 197.
2. Mandatory test details are entered into the LIS.
   Refer to "slide information" on page 198.
3. The LIS submits demographic and test details to the Bond system.

4. The Bond software creates a case with the LIS-submitted details.
   Refer to "working with cases" on page 121.
5. The Bond software creates slides with the LIS-submitted details.
   Slides are assigned to the LIS-specified case.
   Dispense volume and protocol defaults may be edited (unless specified by LIS).
   Refer to "working with slides" on page 125.
6. The Bond operator prints slide labels and applies them to the appropriate slides.
   These slides use the LIS slide label configuration (refer to "LIS slide labels" on page 192).
   The LIS slide label configuration is compatible with the Bond Auto-ID system.
   Refer to "slide labelling" on page 129.
7. The slides are loaded onto a Bond Processing Module and are automatically recognized by the Bond system.
   Refer to "automatic slide identification" on page 108.
8. The Bond operator starts the batch and the slides are processed.
   Refer to "running a protocol" on page 98.

scenario 4 — externally printed slide labels

Patient demographics (case)	LIS
Tests (slides)	LIS
Slide labels	Externally printed, assisted-ID
Data transfer method	LIS submission

The following is a workflow outline for a Bond LIS-ip configuration with LIS demographic data, LIS test data, assisted-ID, externally printed slide labels and LIS data submission.

1. Slides are labelled with external labels.
   These labels may be printed from the LIS, printed from another application or may be handwritten.
   The Bond auto-ID system does not work with externally printed labels.
2. Mandatory demographic details are entered into the LIS.
   Refer to "case information" on page 197.
3. Mandatory test details are entered into the LIS.
   Refer to "slide information" on page 198.
4. The LIS submits demographic and test details to the Bond system.
5. The Bond software creates a case with the LIS-submitted details.
   Refer to "working with cases" on page 121.
6. The Bond software creates slides with the LIS-submitted details.
   The slides are assigned to the LIS specified case.
   the dispense volume and protocol defaults may be edited (unless specified by the LIS).
   Refer to "working with slides" on page 125.
7. The slides (with non-compatible labels) are loaded onto a Bond Processing Module.
8. Bond displays an image of each slide label to assist the operator as they match each slide to a pending test.
   Refer to "assisted slide identification" on page 109.
9. The Bond operator starts the slide batch and the slides are processed.
   Refer to "running a protocol" on page 98.

12

cleaning and maintenance

Warning
When operating inside the Bond™ Processing Module (for example, daily cleaning around the Slide Staining Assemblies) you should switch the Processing Module off. Even though interlocks should prevent operation when the lid is opened, this will add an extra level of security.

Warning
Hazardous fluids may collect in various parts of a Processing Module.
Always wear protective clothing and gloves when working with the Processing Module and components, including reagent containers.
Immediately clean up spills using standard laboratory practice.

Bond-max

Warning
Slide Staining Assemblies in the Bond-max may be very hot and cause severe burns. Do not touch the Slide Staining Assemblies or their surrounds within twenty minutes of cessation of operation of a Processing Module.

Caution
Clean all removable components by hand only. To avoid damage, do not wash any component in an automatic dishwashing machine.
Do not clean any part with solvents, harsh or abrasive cleaning fluids, or harsh or abrasive cloths.

This chapter gives procedures for cleaning and maintenance tasks. Whenever you perform these tasks, and especially after replacement procedures or after servicing, look for leaks, or worn or damaged equipment. Locate and fix the source of leaks, and replace worn or damaged equipment as necessary.

12.1 cleaning and maintenance schedule

Task	Section
Before starting	
Ensure the system is primed. The Processing Module primes when it is turned on. If you leave the Processing Module turned on around the clock, then you should schedule a time to turn it off and on again once during the day.	
Check tubing connected to the aspirating probe for blockages and bubbles.	12.2
Check the Covertile™ clamps.	12.4
Check that bulk and hazardous waste containers have plenty of space. Empty if necessary. Check that the bulk reagent containers have enough reagent for the daily operation. Refill if necessary.	12.11
End of run or daily	
Clean the aspirating probe. Check tubing for blockages and bubbles.	12.2
Clean each Slide Staining Assembly.	12.3
Clean the Covertiles.	12.5
Clean the slide trays.	12.6
Shut down the software, and turn off the Processing Module for more than 30 seconds.	
Weekly	
Clean the covers and lid.	12.7
Clean the lower drip tray (upon which the bulk reagents sit).	12.9
Top up buffer, alcohol, and DI water.	12.11
Clean the robot arm ID imager.	12.12
Clean the external ID scanner.	12.13
Clean the Slide Labeller.	12.14
Check syringe tightness	12.15
Monthly	
Replace the mixing station (based on a usage rate of 60 slides per day, alter frequency if more or less slides are run).	12.8
Clean all bulk containers.	12.11
6 Monthly	
Replace the aspirating probe and tubing.	12.2
Change the syringe and tip	12.15

12.2 aspirating probe

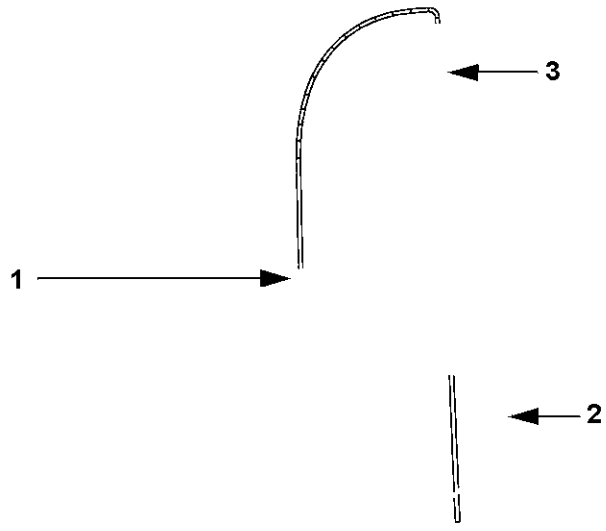


Figure 154: Diagram of the aspirating probe assembly
(The numbers are referred to in the text)

12.2.1 cleaning

Clean the aspirating probe by carefully wiping the tip using a 70% alcohol solution on a soft cloth.

Inspect the tubing attached to the aspirating probe, and ensure that there are no kinks or objects inside the tubing. The tubing should be clean.

12.2.2 replacement

The aspirating probe is supplied as an assembly of the tube and insulation, along with tubing and connector. The connector attaches the tubing to the "chain" on the left of the robot arm; the aspirating probe is inserted through the aspirating probe rack on the right of the robot arm.
You do not need tools to replace the aspirating probe. To prepare the fluidics system prior to removing the aspirating probe, run the "Change syringe" function from the maintenance menu.

removing the aspirating probe

Remove the aspirating probe assembly as follows:

1. Ensure all Processing Modules are idle and have no batches loaded, scheduled or running.
2. From the *Maintenance* menu select the appropriate Processing Module then select "Change syringe" (see Figure 155).

Figure 155: Change syringe option in the Maintenance menu

3. The Replace syringe dialog will now appear.
   Carefully read the instructions then click **Yes** to continue.
   If you click **No**, the syringe replacement procedure will terminate.
4. The Processing Module will now prepare the fluidics system for the aspirating probe replacement.
5. When the Processing Module disconnects, switch off the Processing Module and the host computer.
6. Open the Processing Module's lid.
7. Unscrew the tube from the "chain" on the left of the robot arm.
   Do this by unscrewing the connector at position 1 in Figure 154.
8. Fully loosen the knurled nut on the front of the liquid level sensor block (item 2 in Figure 154).
   A bracket prevents the screw from falling.

If you do not fully loosen the nut you may damage the Teflon coating on the aspirating probe. You must fully loosen the nut before replacing the aspirating probe. The bracket will hold the nut in place.

9. Hold the exposed tip below the liquid level sensor block, and push the aspirating probe up to ensure it is loose.

   (Do not pull the tubing from the top of the aspirating probe rack (item 3 in Figure 154), as this may dislodge the tubing from the tip).
10. Pull the tubing up through the aspirating probe rack and remove the aspirating probe.

installing a new aspirating probe

Install the new aspirating probe assembly as follows, being careful not to damage the exposed tip:

1. Ensure the aspirating probe rack is fully raised.
2. Carefully remove the aspirating probe from its protective container.
3. Feed the aspirating probe into the aspirating probe rack until the tip of the aspirating probe emerges from the rack, then stop.

   You may need to carefully jiggle the aspirating probe to feed the tip through the liquid level sensor block—severe force should not be required.
   If the aspirating probe stops without emerging a service call may be required.
4. Hold the aspirating probe rack with one hand and the aspirating probe tip with the other.
   Pull the aspirating probe down slowly but firmly until you are certain it has reached the top.
5. While still holding the aspirating probe down, tighten the knurled nut at the front of the liquid level sensor block (item 2 in Figure 154) until a slight resistance is felt.

   Do not over-tighten, as this may damage the aspirating probe.

   Check to see if the aspirating probe tip can be rotated or slid up or down without using excessive force. It should not move.
6. Connect the tube "chain" block (item 1 in Figure 154).
   Ensure the fitting is screwed tightly into the chain block.
7. Make sure that the aspirating probe rack is fully raised, then turn the Processing Module on.
   The Processing Module will prime the system when it is started—check the connections and the tip of the probe to ensure that there is no fluid leakage while the system is priming, and during the first run.

12.3 slide staining assembly

Before cleaning or maintaining the Slide Staining Assemblies, ensure the Processing Module has finished any runs and turn the power off.

Bond-max

Warning

The Slide Staining Assemblies, and therefore their surrounds and the slides in the Slide Staining Assemblies, may be hot enough to cause severe burns if touched.
Do not touch a Slide Staining Assembly until the software indicates that the temperature is cool. If the software is not running, allow at least twenty minutes after power has been disconnected from the Processing Module.

12.3.1 cleaning

To clean the Slide Staining Assembly, use a cloth and a 70% alcohol solution to wipe the top plate, Covertile clamps, and wash-plate. To gain access to the Covertile clamps and wash plate you will need to unfasten and swing the top plate as described in "removing a top plate" on page 209 following. It is not necessary to completely remove the top plate for cleaning.

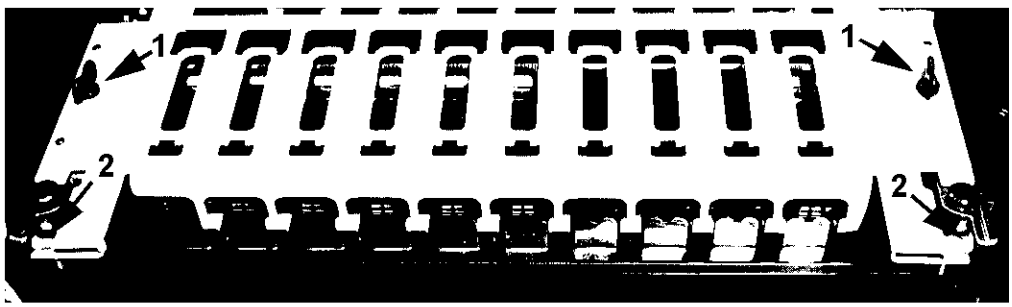


Figure 156: Top plate showing (1) twist fasteners, and (2) pivot hinges

As you clean the Slide Staining Assembly and its components, check for any warping or permanent damage. Warped top plates should be replaced, as warping may affect how well the slides are held in position, and therefore may affect the quality of staining.

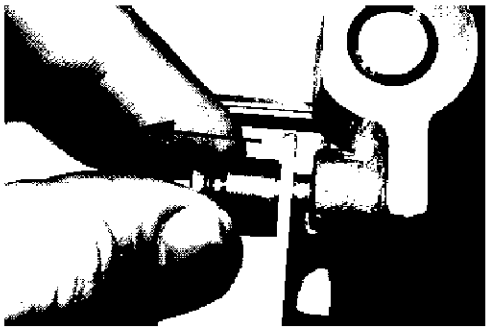
Contact a service representative if there is any damage to components of a Slide Staining Assembly.

When you have finished cleaning the plate, close it, checking that holes at each end of the plate correctly engage the locating pins. Hold down the top plate and turn the twist fasteners clockwise. They should clamp firmly with a quarter turn clockwise.

12.3.2 removing a top plate

To remove a top plate do the following:

1. Open the top plate by pushing it down and turning the twist fasteners anti-clockwise.
   Swing the top plate back on its hinges.
2. Remove the top plate by pulling the spring-loaded pivot fasteners at each end of the plate, then lifting the plate away from the Slide Staining Assembly.



12.3.3 replacing a top plate

To replace a top plate:

1. Locate the pivot points in the Slide Staining Assembly. Hold the top plate in the open position, and place one of the pivot fasteners into the pivot point of the Slide Staining Assembly.
   The top of the plate should be facing away from the Slide Staining Assembly.
2. Pull the other pivot fastener, put the end of the plate in position, and release the fastener.
3. Close the top plate, checking that holes at each end of the plate correctly engage the locating pins.
4. Hold down the top plate and turn the twist fasteners clockwise.
   They should clamp firmly with a quarter turn clockwise.

12.3.4 manually unlocking slide staining assemblies

Each Slide Staining Assembly can be unlocked manually, for example to remove slides in a power failure.

To manually unlock Slide Staining Assemblies, you must remove the bulk containers and upper drip tray, then unlock the assembly or assemblies containing the slides that you wish to recover.

Warning
The Slide Staining Assemblies contain moving parts that can cause serious injury.
Before attempting to manually unlock the Slide Staining Assemblies, turn the Processing Module power switch off, turn the mains power off, and disconnect the mains power supply plug from the mains supply at the wall to prevent unexpected operation.

Warning
During this procedure you will handle hazardous waste containers and operate around areas where reagents and possibly hazardous fluid may have been spilt.
Wear gloves and take appropriate precautions when following this procedure.

To manually unlock a Slide Staining Assembly, do the following:

1. Turn off the mains power and remove the power cable.
2. Open the bulk reagent door and remove the bulk containers.
3. Slide the tray at the top of the bulk reagent cavity tray out.
4. Locate the manual release knob beneath the Slide Staining Assembly.

Figure 157: Manual release knob

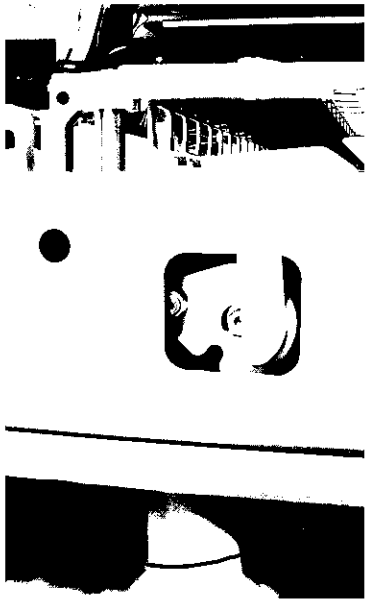


Figure 158: Turn the knob to release the slides

5. Turn the knob in the direction shown in Figure 158. As you do the Covertiles should be moved over the slides and the whole assembly and tray will move up.
6. Continue turning the release knob until you feel a resistance. At this point it should be possible to remove the slide tray from the assembly.
7. Store your slides according to procedures at your site.
8. Clean the lower and upper drip trays, if necessary, then re-insert the upper drip tray—the end of the tray with the 45 degree bend goes to the front, with the angle upwards.
9. Re-insert the bulk containers.
10. Close the bulk reagent cavity door.

When the Processing Module is powered up again, it will detect the state of the assemblies and take any actions necessary to ready them for use. You can view the Protocol Status screen (see "protocol status screen" on page 117) to see the steps of the protocol that were completed, then finish the remaining steps manually.

12.4 covertile clamps

You should inspect the Covertile clamps at least weekly. If any are damaged, or there are any feet that do not spring back when pressed, contact your service representative.

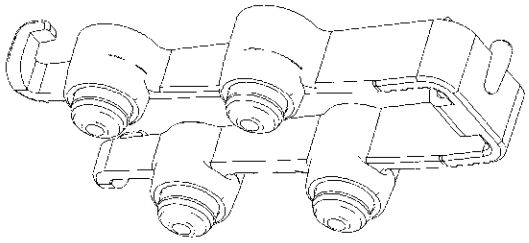


Figure 159: Covertile clamp

12.5 covertiles

The Covertiles can be reused up to 25 times provided they are not discolored or damaged, and provided they are cleaned properly.

To reuse a Covertile, inspect it closely for chips, cracks, bending, warping, or any other signs of damage. If the Covertile looks undamaged, clean it using 70% alcohol.
When clean, check that the Covertile is not discolored.

Discard damaged or discolored Covertiles.

12.6 slide trays

Clean slide trays with 70% alcohol. Replace deformed or damaged trays.

12.7 covers and lid

Use a damp lint free cloth to dust the covers and lid to prevent accumulation of dirt.
If any of the covers or the lid becomes deformed or damaged, contact your service representative for a replacement.

12.8 mixing station

The mixing station contains six wells for mixing reagents. It fits as an insert in the wash block.

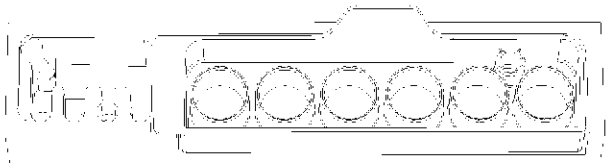


Figure 160: Top view of wash block with mixing station in place

The mixing station carries an ID. Do not remove this ID, as the Bond system must read it to operate correctly. If the ID is not found, the Bond system will assume that the mixing station is not available, and will not initialize.

You should replace the mixing station monthly (based on a usage rate of 60 slides per day, alter frequency if more or less slides are run). To remove the mixing station, grasp the tab at the back of the mixing station and lift out.
Ensure that when you replace the mixing station the tab is at the back of the wash block.

12.9 bulk reagent drip tray

To clean this tray, first remove all bulk containers, then slide the tray out, noting the orientation. The tray is not symmetrical and must be placed in the correct orientation.

Clean by wiping with 70% alcohol solution.

12.10 reagent trays

Clean the reagent trays with a 70% alcohol solution.

Caution
Do not use hot water or solvents to clean reagent trays, and do not autoclave.
Hot water, solvents, or autoclaving may warp the rack.

Rest the reagent tray upside down and allow to drain, or wipe dry.

12.11 bulk containers

Warning
Some of the reagents used in immunohistochemistry and *in situ* hybridization are hazardous, especially chromogenic reagents, which are carcinogenic via skin contact.
Wear gloves and take care when handling waste containers.

To replenish bulk reagent containers, or empty bulk or hazardous waste containers:

1. Ensure that the Processing Module is not in operation.
2. Open the bulk container door.
3. Pull the container out of the storage area.

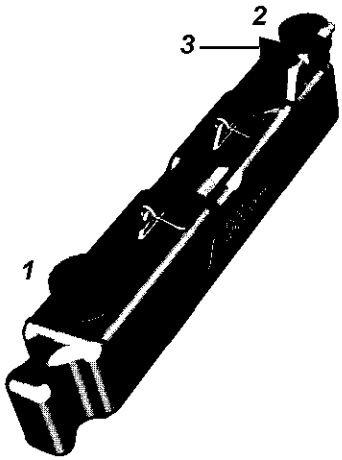


Figure 161: Bulk container showing (1) fill/empty cap; (2) liquid level sensor cap, and (3) connector

- For waste, open the lid (item 1 in Figure 161) and dispose of the waste in accordance with approved procedures at your site.

Do not remove the liquid level sensor cap.

- For bulk reagent, place the container on a level surface, open the lid, then fill as required.

4. Locate the connector in the correct receptacle at the back of the storage area, then push home to ensure a leak-tight connection.

For routine cleaning of bulk reagent containers, use Decon or similar detergent and rinse with deionized water.

Every month, empty the reagent containers and clean them using bleach or an industrial strength detergent, then rinse thoroughly with deionized water.

external waste container

This is optional in the Bond-x system, and must be installed by a service representative.
To empty the external waste container:

Disconnect the liquid level sensor cable before opening the waste container cap. This prevents the system from flushing waste to the external waste tubing.
Only connect the sensor when the cap and waste tubing is in place.

1. Disconnect the liquid level sensor cable from the bottle cap by unscrewing the parts of the metal connector near the cap, then separating.
2. Press the metal button on the waste tubing connection to the container cap.
3. Remove the cap and dispose of the waste according to approved procedures at your site.
4. Replace the cap, then press the waste tubing connector until it clicks into place.
5. Reconnect the liquid level sensor cable.

12.12 robot arm and ID imager

Caution
Turn the Processing Module off when cleaning the robot arm to minimize the risk of any short circuits from fluid drops.
Do not use a wet cloth to clean the ID imager, as leaving moisture on the window may cause errors.
Do not use alcohol or solvents to clean the window.

To clean the robot arm, dampen a cloth with 70% alcohol and wipe the arm. Avoid wiping the aspirating probe rack, as this may dissolve the lubrication. Also, do not clean the racks that the robot arm moves along—this will remove the lubrication and may degrade the performance of the Processing Module.

Every week, or if the imager frequently fails to properly image IDs, clean the window with a cotton wool bud or a lint-free cloth moistened with distilled water.

12.12.1 re-initializing the processing module's ID imager

If the Processing Module's ID imager is not operating correctly, your service organization may request that it be re-initialized.

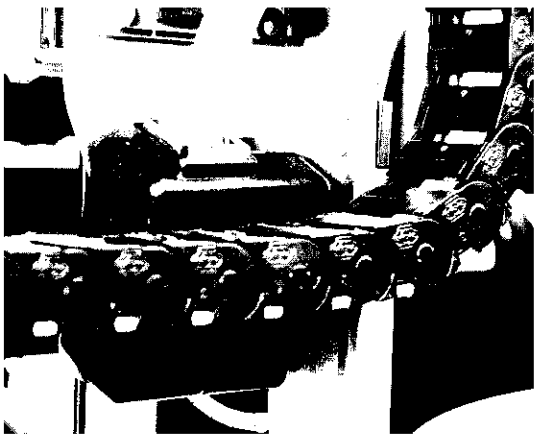


Figure 162: ID imager

Use the following instructions to re-initialize the Processing Module's ID imager.

1. Ensure the Processing Module is on and that no batches are currently running and no slide trays are locked.
2. Open the Processing Module's lid.
3. Place the initialization image (Figure 163) under the ID imager.

Figure 163: Initialization image

4. Insert a paper clip (or similar) into the small hole on the side of the imager (Figure 164) and press it until you feel it activate the internal button.

Figure 164: Re-initializing the ID imager

5. The system will now attempt to initialize using the image.
   Watch the image closely and ensure the green alignment beam is situated over the center as shown in Figure 165.

Figure 165: Image alignment

6. If successful, you will hear a two-tone beep that indicates the ID imager has been successfully re-initialized.
7. If you hear no beep, or a longer or shorter beep sequence, initialization was not successful. Reposition the initialization image and try again.

12.13 handheld ID scanner

Warning
Laser hazard.
The ID scanner contains a laser device that may cause severe eye damage.
Do not look into the ID scanner's window while it is switched on.

12.13.1 cleaning

The window of the scanner is sensitive. While cleaning the scanner observe the following precautions:

- Do not allow any abrasive material to touch the window
- Do not spray water or other cleaning liquids directly into the window
- Do not remove the rubber nose of the scanner.

Clean the scanner by:

1. Turning the unit off.
2. Removing dirt particles with a damp, lint-free cloth.
3. Wiping the window using a tissue moistened with distilled water.

12.13.2 identifying scanner type

The Bond system uses either a serial handheld ID scanner or a USB handheld ID scanner. Both scanners operate in an identical manner but have different connection and configuration methods. The images below identify the scanner type.

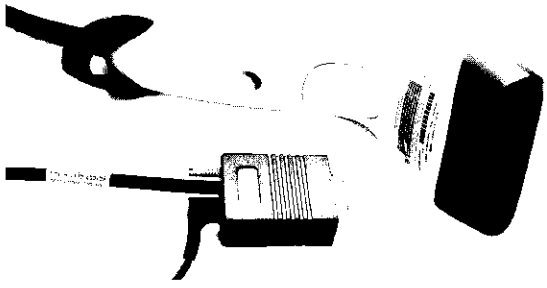


Figure 166: Serial connection

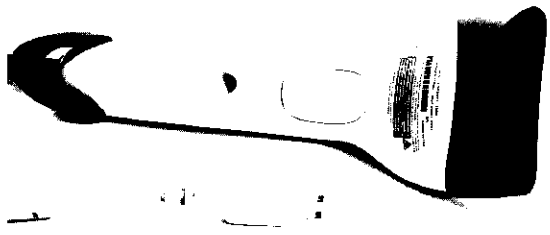


Figure 167: USB connection

12.13.3 connection

The handheld ID scanner may connect to either a serial or USB port on the host computer (refer to "identifying scanner type" on page 216). If the ID scanner is replaced the ID scanner port setting may need to be altered. This will normally be done by your service organization but you may adjust the setting if required. Please refer to "ID scanner port settings" on page 74 for details.

12.13.4 configuration

If the handheld ID scanner is not operating correctly, your service organization may request that it be re-initialized. You may also adjust the beeper volume if you have a serial scanner.

Before you begin this procedure you must first identify the type of handheld ID scanner installed on your system.

- If the connector on your scanner is the same as that shown in Figure 166, it has a serial connection and you must use the instructions in "configuring a serial ID scanner" on page 217.
- If the connector on your scanner is the same as that shown in Figure 167, it has a USB connection and you must use the instructions in "configuring a USB ID scanner" on page 218.

configuring a serial ID scanner

To re-initialize a handheld ID scanner with a serial connection, you must scan each of the following bar codes in turn.

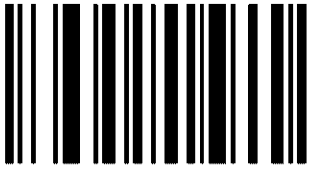


Figure 168: Set all defaults

Figure 169: Standard RTS/CTS

Figure 170: Odd

Figure 171: OPOS/JPOS

To set the beeper volume for a serial handheld ID scanner, scan the bar code below that corresponds to the desired level.

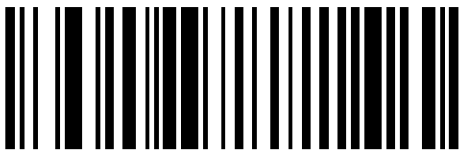


Figure 172: Low volume

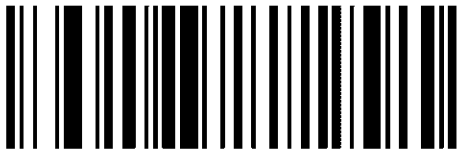


Figure 173: Medium volume

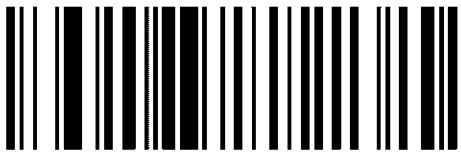


Figure 174: High volume

configuring a USB ID scanner

To re-initialize a handheld ID scanner with a USB connection, you must scan each of the following bar codes in turn.

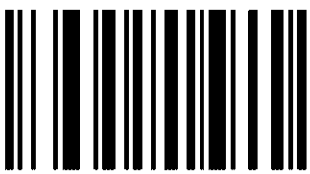


Figure 175: Set all defaults

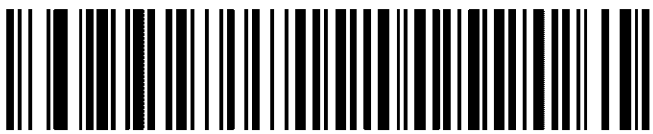


Figure 176: IBM handheld USB

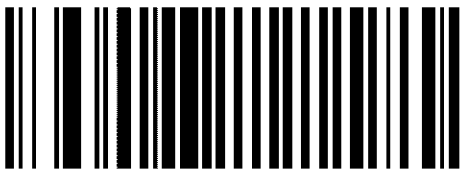


Figure 177: Enable code 128

12.14 slide labeller

Manuals are provided with the Slide Labeller. Refer to these for instructions on cleaning and loading labels and printing ribbon.

12.15 syringe

The syringe pump aspirates and dispenses the precise fluid volumes required by the Bond system. The plunger forms a complete seal inside the tube. The glass tube and the plunger must be free of damage to ensure accurate fluid volumes are aspirated and dispensed. They must be replaced if damaged in any way.

12.15.1 inspection

At least once a week you should check the syringe as follows. If there is any evidence of leaks or if the syringe becomes loose, contact your service representative.

1. Ensure that the Processing Module is not operating.
2. Open the syringe cover (see item 11 in Figure 2 on page 30).
3. Inspect around the connections and below the syringe for evidence of leaks.
4. Using your fingers only, ensure that the glass tube of the syringe is tight on the plastic fitting of the valve.

Do not use any tools to secure or tighten the syringe.

12.15.2 maintenance

The syringe must be replaced every six months. This may be done by your service organization or you may choose to conduct the procedure yourself.

Removing the syringe

Use the following procedure to remove the syringe.

1. Ensure all Processing Modules are idle and have no batches loaded, scheduled or running.
2. From the *Maintenance* menu select the appropriate Processing Module then select "Change syringe" (see Figure 178).

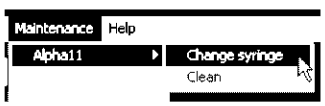


Figure 178: Change syringe option in the Maintenance menu

3. The Replace syringe dialog will now appear.
   Carefully read the instructions then click **Yes** to continue.
   If you click **No**, the syringe replacement procedure will terminate.

4. The Processing Module will now prepare the syringe for replacement. This may take a few minutes.
5. When the Processing Module disconnects, switch off the Processing Module and the host computer.
6. Open the syringe door on the Processing Module's right cover.
7. Loosen the two screws that hold the syringe clamp (see Figure 179).

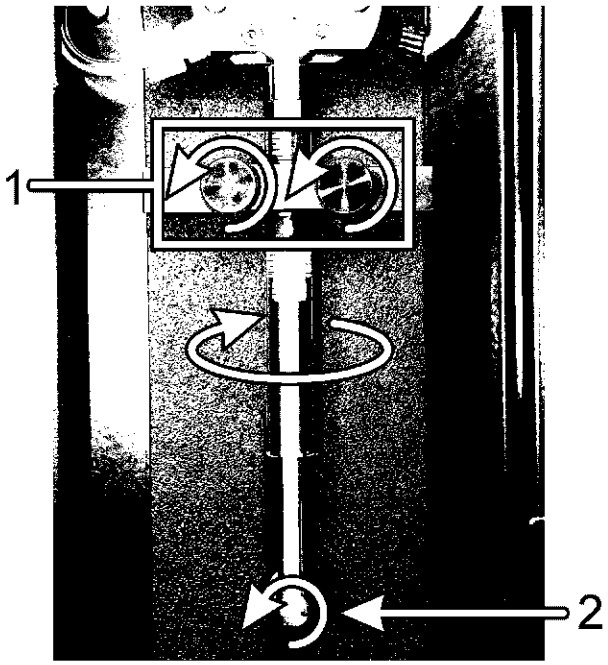


Figure 179: Removing the syringe with clamp screws (1) and plunger screw (2)

8. Remove and retain the thumbscrew holding the plunger to the pull-down arm (see Figure 179).
9. Twist the glass tube in the direction shown in Figure 179 to unscrew it from the syringe valve.
10. Remove the plunger from the glass tube.
11. Completely remove the clamp (including the inner sleeve) from the glass tube.

Replacing the syringe

Use the following procedure to replace the syringe.

1. Slide the sleeve onto the syringe so it is approximately 10 mm from the metal end cap (see Figure 180).

Figure 180: Syringe sleeve in position

2. Fit the top and bottom clamp sections over the sleeve (as shown in Figure 181) but do not completely tighten so the tube can still turn.

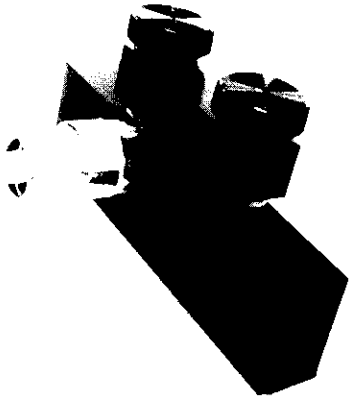


Figure 181: Clamp fitted to syringe

3. Wipe the plunger with alcohol then wait for all the alcohol to evaporate.
4. Wet the tip of the plunger with deionized water.

Air bubbles may form in the system and tissue staining may be compromised if you do not properly prepare the plunger using alcohol and deionized water as described in the previous steps.

5. Fully insert the plunger into the glass tube.
6. Secure the glass tube to syringe valve by pushing the tube up while twisting it one full turn in the direction shown in Figure 182.
   Do not use any tools to secure or tighten the syringe.
   The connection must be tight or air will leak into the system.

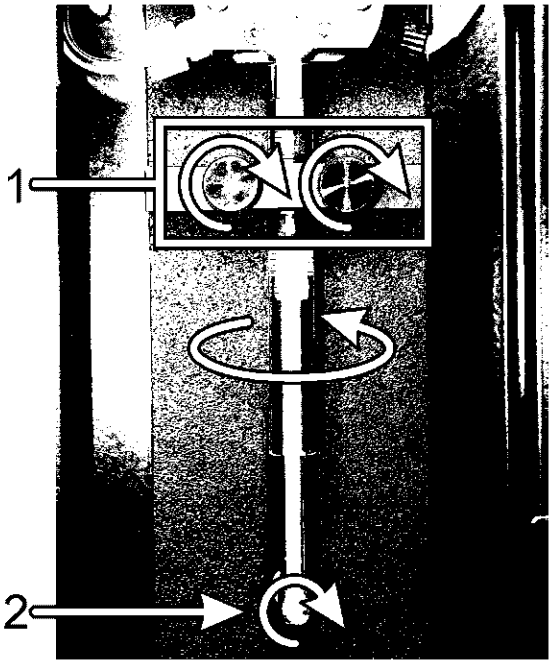


Figure 182: Replacing the syringe with clamp screws (1) and plunger screw (2)

7. Tighten the two clamp screws to secure the tube (see Figure 182).
   The clamp should be approximately 10 mm from the metal end cap.
8. Secure the plunger to the pull-down arm using the thumbscrew (see Figure 182).
9. Close the cover door.
10. Restart the Processing Module and host computer.
11. Check that the Processing Module primes correctly and that there are no air bubbles or leaks around the syringe.

12.16 back panel

The following diagram (Figure 183) describes the features on the back panel of the Bond Processing Module.

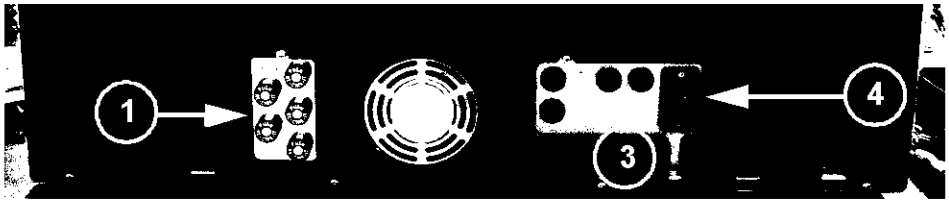


Figure 183: Lower part of rear panel

1. Circuit breakers
2. Power supply fan
3. Fuses
4. Mains power connection

12.16.1 disconnecting the processing module

To disconnect the Processing Module from the mains power supply, do the following:

1. Switch off the power using the switch at the right side of the Processing Module.
2. Trace the power cable from the mains Processing Module mains power connection (item 4 in Figure 183) to the wall. Switch off the mains power supply at the wall socket.
3. Disconnect the plug from the back of the Processing Module.

12.16.2 power supply fuses

Caution
Never bypass or short-circuit fuses by any means. Replace fuses only with standard parts.

To replace the fuses, do the following:

1. Turn off the Processing Module.
2. Switch off the mains power supply and disconnect the mains power supply from the wall socket.
3. Gently push the fuse cover while turning left one quarter turn.
4. Pull out the fuse cover and replace the fuse.
5. For continued protection against risk of fire, replace only with fuses as stated on the label on the Processing Module.
6. Push the fuse cover and turn to the right to lock the fuse in position.

13

using bond reagents

13.1 principle of the procedure

immunohistochemistry (IHC)

Immunohistochemical techniques have been used to detect specific antigens in cells or tissue for at least 50 years. The first reported method used fluorescent labels in 1941[1]. Subsequently, enzymatic markers, such as peroxidase, were introduced[2]. Today immunohistochemistry is used to facilitate cell recognition alongside routine H & E paraffin stains, and is an aid to the recognition of normal and abnormal cells. Immunohistochemical methods have become the "standard of care" in surgical pathology when classic methods alone fail to yield a definitive diagnosis[3,4]. However, there have been some reservations concerning reproducibility[5], despite almost universal adoption.

Reagents on the automated Bond™ system demonstrate antigens in tissue sections by immunohistochemical techniques. In summary, a specific primary antibody binds to a section, then Bond detection system reagents visualize the complex.

in situ hybridization (ISH)

Molecular biological techniques have largely advanced our understanding of disease. In situ hybridization combines both molecular biology and histology, allowing visualization of DNA or RNA in their cellular context. Since nucleic acid detection was first introduced in 1969[6], improvements to in situ hybridization protocols have made it an increasingly valuable tool for clinical pathology as well as research.

In situ hybridization utilizes the complementary binding of nucleotide bases in DNA or RNA. A labelled nucleic acid probe binds specifically to its complementary sequence in fixed tissue or cell specimen. The probe is visualized through the application of an antibody against the label followed by Bond polymer detection reagents. The Bond automated system and reagents offer a reliable and efficient alternative to a cumbersome manual technique.

13.1.1 bond detection systems

Vision BioSystems™ supplies a range of detection systems developed specifically for Bond. Foremost amongst these is the Bond Polymer Refine Detection system, which provides high intensity staining coupled with sharp definition without the use of streptavidin and biotin.

The Bond detection systems available are listed in the sections below.

bond polymer detection systems (DAB)

These DAB-based systems avoid the use of streptavidin and biotin, and therefore eliminate nonspecific staining as a result of endogenous biotin. Endogenous biotin is prevalent in some tissues such as gastrointestinal tract, kidney, liver, and breast carcinoma. Bond polymer detection systems have higher sensitivity than labelled streptavidin-biotin systems, resulting in higher primary antibody dilutions.

There are three Bond Polymer Detection Systems:

- Bond Polymer Refine Detection: the premier Bond Detection System. Delivers high intensity staining coupled with sharp definition of membrane-bound antigens or target nucleic acid sequences.

  There is no impact on the specificity of the staining when using Refine detection — rather, one sees a sharper delineation of antibody binding to the target antigen or probe binding to the nucleic acid. If a stronger intensity is desired the following options are available:

  (i) Increase the incubation times for the primary antibody or probe and/or detection system components.

  (ii) Use a Bond DAB Enhancer step. Note that an enhancer alone will not increase the level of staining intensity to the same extent as that produced by Intense detection system.

  (iii) For IHC only, increase the primary antibody concentration.

- Bond Polymer Intense Detection: suitable for applications that require intense deposition of DAB reaction product — produces strong immunostaining and maximizes sensitivity.
- Bond Polymer Define Detection: the reaction product is deposited in sharp, clearly defined areas that allow a more detailed visualization and localization of membrane-bound antigen within tissues, for example CD markers and HER2. Staining intensity will often be decreased relative to Intense or Refine.

The steps used in these detection systems are:

1. Incubation with hydrogen peroxide.
2. Application of the specific primary antibody or probe.
3. A post antibody treatment that prepares the tissue for the penetration of the subsequent polymer reagent.
4. Incubation with the polymer reagent, which comprises polymeric horseradish peroxidase (HRP)-secondary antibody conjugates that recognize both mouse and rabbit immunoglobulins.
5. Visualization of the complex with DAB.
6. Hematoxylin counterstaining allows the detection of cell nuclei.

Incubation, washing, and interpretation of results are carried out as described for Bond Labelled Streptavidin-Biotin Detection Systems.

bond polymer AP red detection system (fast red)

The Bond Polymer AP Red Detection System has the same advantages as the DAB-based polymer detection systems described above, but Fast Red chromogen is used for visualization instead of DAB. The system is suited for use on tissues such as skin where tissue pigments can be mistaken for DAB.

Fast Red chromogen is chemically unstable in normal laboratory conditions. Be sure to strictly follow user instructions for Bond Polymer AP Red Detection System to maintain its efficacy. Always place control tissue on the same slide as patient tissue to allow rapid detection of any deterioration in the system.

The steps are:

1. Application of the specific primary antibody.
2. A post antibody treatment that prepares the tissue for the penetration of the subsequent polymer reagent.
3. Incubation with the polymer reagent, which comprises polymetric alkaline phosphatase (AP) secondary antibody conjugates that recognize both mouse and rabbit immunoglobulins.
4. Visualization of the complex with substrate chromogen, Fast Red, via a red precipitate.
5. Hematoxylin counterstaining allows the detection of cell nuclei.

Incubation, washing, and interpretation of results are carried out as described for Bond Labelled Streptavidin-Biotin Detection Systems.

bond labelled streptavidin-biotin detection systems (DAB)

These are:

- Bond Intense Detection
- Bond Intense R Detection
- Bond Define Detection

These DAB-based detection systems operate as follows:

1. Incubation with hydrogen peroxide to quench endogenous peroxidase activity.
2. Application of the specific primary antibody.
3. The antibody is localized by a biotin conjugated secondary antibody formulation that recognizes mouse or rabbit immunoglobulins.
4. Addition of a streptavidin-enzyme conjugate that binds to the biotin present on the secondary antibody.
5. Visualization of the complex with a substrate chromogen (3,3'-diaminobenzidine, or DAB), whose enzyme product is a brown precipitate.
6. Counterstaining with hematoxylin allows the detection of cell nuclei (blue).

At each step the Bond system incubates the sections for a precise time, then washes the sections to remove unbound material. Results are interpreted using an optical microscope, and aid in the differential diagnosis of pathological processes, that may or may not be associated with a particular antigen.

13.2 specimen preparation

13.2.1 materials required

The following materials are required for immunohistochemical and in situ hybridization staining using the Bond system.

IHC with retrieval and ISH require Bond-max systems.

common materials

- One or more Processing Modules
- Bond-x System Processing Module (Catalog No. 21.0000.110) and Bond-x System Control Kit (Catalog No. 21.1900.110)
- Bond-max System Processing Module (Catalog No. 21.0051.110) and Bond-max System Control Kit (Catalog No. 21.1950.110)
- Fixative — recommended 10% Neutral buffered formalin
- Paraffin wax
- Tissue processor or embedding center
- Positive and negative tissue controls (see "quality control" on page 230)
- Microtome
- Charged microscope slides (e.g. Vision BioSystems Plus Slides, Catalog No. S21.1910.110)
- Drying oven
- Xylene (histological grade) [Bond-x]
- Alcohol (histological grade) [Bond-x]
- Bond Dewax Solution (Catalog No. AR9222) [Bond-max]
- Deionized water
- Bond Enzyme Pretreatment Kit (Catalog No. AR9551) [Bond-max]
- Bond Universal Slide Labels (Catalog No. S21.2011.110)
- Bond Universal Covertiles (Catalog No. S21.2001.110)
- Bond wash solution (prepared from Bond Wash Solution 10X Concentrate, Catalog. No. AR9590)
- Appropriate Bond detection system
- Mounting medium, resin-based or aqueous-based
- Coverslips
- Light microscope (4-40X)

materials for IHC

IHC In addition to the materials listed above, the following are required for IHC tests:

- Negative control reagents specific to primary antibodies (see "quality control" on page 230)
- Staining jars or baths [Bond-x]
- Materials for epitope retrieval specific to primary antibodies [Bond-x]
- Bond Epitope Retrieval Solution 1 (Catalog No. AR9961) [Bond-max]
- Bond Epitope Retrieval Solution 2 (Catalog No. AR9640) [Bond-max]
- Bond ready-to-use primary antibodies, or primary antibodies diluted in Bond Primary Antibody Diluent (Catalog No. AR9352) in Bond Open Containers, 7 mL (OP79193) or 30 mL (OP309700)
- Mounting medium, resin-based or aqueous-based
- Bond Slide Preparation Tray, optional (Catalog No. S21.1970.110).
- Titration kit, optional (see "titration kit" below)

materials for ISH

ISH In addition to the common materials listed above, the following are required for ISH tests:

- ISH probes
- Anti Fluorescein Antibody (Catalog AR0833)
- Positive and Negative Control Probes specific to ISH (see "quality control" on page 230)

titration kit

IHC Bond Titration Kit consists of 10 empty containers and 50 inserts (6 mL) and is used when optimizing the concentration of primary antibodies for the Bond system. Small volumes of each primary antibody concentration can be prepared and placed into the inserts. Each container may be used for a total of 40 mL of reagent.

Titration of concentrated antibodies can be achieved using serial two-fold dilutions. The following method describes how to prepare serial dilutions for a 150 µL single dispense.

1. Label three inserts with appropriate dilutions for each antibody.
2. Make a starting dilution in the first insert of 700 µL.
3. Dispense 350 µL of Bond Primary Antibody Diluent into insert 2 and 3.
4. From the starting dilution, transfer 350 µL to insert 2 and gently mix.
5. From insert 2, transfer 350 µL to insert 3 and gently mix.

13.2.2 tissue preparation

We recommend 15 to 20 times the volume of tissue of 10% neutral-buffered formalin to fix tissue for immunohistochemical and in situ hybridization staining using the Bond system. For example, a 3 mm or smaller section of tissue will be optimally fixed in 4 hours[9]. Fixation can be performed at room temperature (15–25 °C).

To facilitate tissue cutting and prevent damage to microtome blades, decalcify osseous tissues prior to tissue processing[10,11].

The US Clinical Laboratory Improvement Act (CLIA) of 1988 requires in 42 CFR 493.1259(b) that "The laboratory must retain stained slides at least ten years from the date of examination and retain specimen blocks at least two years from the date of examination."[12] Consult local regulations for requirements at your site.

Cut and pick up 3–5 µm thick sections on charged glass slides. CNS tissue requires 8–10 µm sections. To dry tissue place the slides in a 60 °C (±5 °C) oven for 10–30 minutes, or overnight at 37 °C. Slides can also be baked on the Bond-max system. Slides must be well air-dried before baking on Bond. Consult references 13, 14 and 15 for further details on specimen preparation.

Affix Bond Universal Slide Labels (Catalog No. S21.2011.110) to specimen and control slides as described in "quick start" on page 86. Users of the Bond-x system need to dewax and rehydrate sections, followed by manual epitope retrieval, according to the method appropriate for the particular primary antibody.

Dewax, rehydration, and epitope retrieval are performed on the Bond-max system.

13.2.3 dewaxing and baking

Paraffin-embedded tissue sections for immunohistochemistry must first have the paraffin wax removed and the section rehydrated. On the Bond-max system, the wax is removed using Bond Dewax Solution and the sections are rehydrated. The Bond system includes Dewax protocols that automate this process.

Prior to dewaxing, Bond can also bake the tissue to improve its adhesion to the slide. The Bond Bake and Dewax protocols automate both the baking and dewaxing processes.

Please note that tissue must be air-dried to remove any water before it is placed into the Bond Processing Module for baking and dewaxing.

13.2.4 retrieval

Formalin fixation of tissue causes cross-linking between the aldehyde and amino groups in the tissue and the formation of these bonds can result in variable loss of antigenicity due to the masking effect. Formalin can also form methylene bridges which can change the overall three-dimensional shape of the epitope. Some epitopes are formalin-sensitive and show reduced immunoreactivity after formalin fixation whilst others are formalin-resistant.

Nucleic acids are surrounded by proteins, therefore permeabilization of tissue is needed to make target sequences accessible to the probe.

Epitope retrieval[7,8] can be achieved either by using heat induced epitope retrieval (HIER), enzyme pretreatment, or by a combination of both. HIER is the most extensively used method of epitope retrieval for IHC. The mechanism of HIER is not completely understood. The hypothesis is that heating the section to a high temperature in an epitope retrieval solution hydrolyzes the cross-linkages formed in formalin fixation. This results in remodification of the epitope which can then be stained by immunohistochemistry. The important factors in HIER are temperature, time and pH of the retrieval solution. There are two different epitope retrieval solutions for use on the Bond system: a citrate-based buffer and an EDTA-based buffer.

Enzyme pretreatment uses proteolytic enzymes to break peptide bonds to expose the epitope/target nucleic acid sequence. The enzyme concentration and incubation time is proportional to the fixation time of the specimen and should be optimized accordingly. Enzyme pretreatment is only suitable for some epitopes but is used frequently in ISH protocols.

13.3 quality control

Differences in tissue processing and technical procedures in the user's laboratory may produce significant variability in results, necessitating regular performance of in-house controls in addition to the following procedures. Consult the quality control guidelines of "Special Report: Quality Control in Immunohistochemistry"[3] and/or the Proposed NCCLS guidelines for IHC[13].

Controls should be fresh autopsy/biopsy/surgical specimens fixed, processed and embedded as soon as possible in the same manner as the patient sample(s). Such a control monitors all steps of the analysis, from tissue preparation through to staining.

13.3.1 assay verification

Prior to initial use of an antibody, probe or staining system in a diagnostic procedure, verify the specificity of the antibody/probe by testing it on a series of in-house tissues with known expression representing known positive and negative tissues. Refer to the procedures outlined above and to the quality control recommendations of the CAP Certification Program14 for Immunohistochemistry and/or the NCCLS IHC guidelines[13]. Repeat these quality control procedures for each new antibody lot, or whenever there is a change in assay parameters. Quality control cannot be meaningfully performed on an individual reagent in isolation, since the matched reagents, along with a defined assay protocol, must be tested in unison before using a detection system for diagnostic purposes. Refer to each primary antibody package insert for tissues that are suitable for assay verification.

In addition to the above-mentioned assay verification procedures we recommend staining positive tissue controls monthly and comparing them to the same tissue control stained the previous month. Comparison of controls stained at monthly intervals serves to monitor the assay stability, sensitivity, specificity, and reproducibility.

All quality control requirements should be performed in conformity with local, state and/or federal regulations or accreditation requirements.

13.3.2 tissue controls

positive tissue control

- Indicates correctly prepared tissues and proper staining techniques.
- Include one positive tissue control for each set of test conditions in each staining run.
- Tissue with weak positive staining is more suitable than tissue with strong positive staining for optimal quality control and to detect minor levels of reagent degradation[13].
- Using a multi-tissue control slide that contains tissues exhibiting strong, medium and weak antigen density/nucleic acid expression provides wide control coverage.
- If the positive tissue control fails to demonstrate positive staining, results with the test specimens should be considered invalid.
- We strongly recommend that you always run the Bond system with a control tissue on the same slide as the sample tissue to ensure optimum quality control.

negative tissue control

- Examine after the positive tissue control to verify the specificity of the labelling of the target antigen by the primary antibody in IHC or target nucleic acid by the probe in ISH, and to provide an indication of specific background staining (false positive staining).
- The variety of different cell types present in most tissue sections frequently offers negative control sites, but the user should verify this.
- If specific staining occurs in the negative tissue control, results with the patient specimens should be considered invalid.

13.3.3 negative reagent control for IHC

IHC Use negative reagent control for IHC in place of the primary antibody with a section of each patient specimen to evaluate nonspecific staining and allow better interpretation of specific staining

- Recommended ideal control reagent:
  - (i) For monoclonal antibodies use an antibody of the same isotype that is produced from tissue culture supernatant and in the same way as the primary antibody, but that exhibits no specific reactivity with human tissues.
    Dilute this to the same immunoglobulin or protein concentration as the primary antibody using identical diluent (Bond Primary Antibody Diluent, Catalog No. AR9352).
    If fetal calf serum is retained in the neat antibody after processing, fetal calf serum at a protein concentration equivalent to the diluted primary antibody in the same diluent is also suitable for use.
  - (ii) For polyclonal antibodies use an immunoglobulin fraction (or whole serum, if appropriate) of normal or nonimmune serum from the same animal source and the same protein concentration as the primary antibody, using identical diluent (Bond Primary Antibody Diluent, Catalog No. AR9352).
- Bond Primary Antibody Diluent alone may be used as a less desirable alternative to the previously described negative reagent controls.
- The incubation period for the negative reagent control should correspond to that of the primary antibody.
- Use a separate negative reagent control slide for each retrieval method employed (including no retrieval) for a given primary antibody.

- When panels of several antibodies are used on serial sections, the negatively staining areas of one slide may serve as negative/nonspecific binding background controls for other antibodies.
- To differentiate endogenous enzyme activity or nonspecific binding of enzymes from specific immunoreactivity, stain additional patient tissues exclusively with substrate-chromogen or enzyme complexes and substrate-chromogen, respectively.
- The Bond system includes a default negative IHC control reagent named "*Negative". This negative reagent can be selected as the marker for any IHC protocol and the reagent dispensed is either deionized water or Bond Wash.

  The reagent to be dispensed is set by authorized service personnel, however you can view the setting in the Options table (see "options table" on page 82).

Section	Key	Value	Dispenses
General	PABReplacement	1	Deionized water
		2	Bond Wash (default)

13.3.4 reagent controls for ISH

positive reagent control

ISH For in situ hybridization use the Positive Control Probe.

- Use in place of the probe with a section of each patient specimen to provide information on the preservation of nucleic acids in the tissue as well as accessibility of nucleic acids to the probe.
- The protocol for the Positive Probe Control should correspond to that of the test probe.
- If the Positive Control Probe fails to demonstrate positive staining, results with the test specimens should be considered invalid.

negative reagent control

ISH For in situ hybridization use the Negative Control Probe.

- The protocol for the Negative Control Probe should correspond to that of the test probe.
- Use in place of the probe with a section of each patient specimen to evaluate nonspecific staining and allow better interpretation of specific staining
- The incubation period for the negative reagent control should correspond to that of the probe.
- Use a separate negative reagent control slide for each retrieval method employed (including no retrieval) for a given probe.
- To differentiate endogenous enzyme activity or nonspecific binding of enzymes from specific immunoreactivity, stain additional patient tissues exclusively with substrate-chromogen or enzyme complexes and substrate-chromogen, respectively.

13.3.5 the benefits of quality control

The benefits of quality control are summarized in the table below.

Tissue: fixed & processed like patient sample	Specific antibody/ probe with detection system reagents	Positive Reagent control plus same detection system reagents as used with specific antibody/probe	Negative Reagent control [ISH] or nonspecific antibody or buffer [IHC] plus same detection system reagents as used with specific antibody/ probe
Positive tissue control: Tissue or cells containing target antigen/nucleic acid sequence to be detected (could be located in patient tissue). The ideal control is weakly positive staining tissue to be most sensitive to antibody/ nucleic acid degradation.	Controls all steps of the analysis. Validates reagent and procedures used for staining.		Detection of nonspecific background staining
Negative tissue control: Tissues or cells expected to be negative (could be located in patient tissue or positive control tissue)	Detection of unintended antibody cross-reactivity to cells/ cellular components [IHC] Detection of unintended probe cross-hybridization to other nucleic acid sequences or cells/ cellular components [ISH]		Detection of nonspecific background staining
Patient Tissue	Detection of specific staining	Assessment of nucleic acid preservation/tissue fixation and/or retrieval [ISH]	Detection of nonspecific background staining

13.4 interpretation of staining

A qualified pathologist who is experienced in immunohistochemical/in situ hybridization procedures must evaluate controls and qualify the stained product before interpreting results.

The specificity and sensitivity of antigen detection are dependent on the specific primary antibody utilized. To ensure desired staining, optimize each specific antibody on the Bond system, varying the time of incubation and/or the specific antibody concentration. Failure to optimize the specific antibody may result in suboptimal antigen detection.

ISH probes are ready to use and have been optimized for the Bond automated system, however, protocols may need to be modified to achieve desired staining.

13.4.1 positive tissue control

Examine the positive tissue control first to ascertain that all reagents are functioning properly.

When using DAB-based systems, the presence of a brown (3,3′ diaminobenzidine tetrachloride, DAB) reaction product with the target cells indicates positive reactivity. When using the Bond Polymer AP Red Detection System, the presence of a red reaction product with the target cells indicates positive reactivity. If the positive tissue controls fail to demonstrate positive staining, results with the test specimens should be considered invalid.

13.4.2 negative tissue control

Examine the negative tissue control after the positive tissue control to verify the specificity of the labelling of the target antigen/nucleic acid by the primary antibody/probe.

The absence of specific staining in the negative tissue control confirms the lack of antibody/probe cross-reactivity to cells/cellular components.

If specific staining (false positive staining) occurs in the negative external tissue control, results should be considered invalid. Nonspecific staining, if present, usually has a diffuse appearance. Sporadic staining of connective tissue may also be observed in sections from excessively formalin-fixed tissues. Use intact cells for interpretation of staining results. Necrotic or degenerated cells often stain nonspecifically.

13.4.3 patient tissue

Examine patient specimens stained with the primary antibody/probe last.

Positive staining intensity should be assessed within the context of any nonspecific background staining of the negative reagent control. As with any immunohistochemical/in situ hybridization test, a negative result means that the antigen/nucleic acid was not detected, not that the antigen/nucleic acid was absent in the cells or tissue assayed.

If necessary, use a panel of antibodies to identify false negative reactions.

13.5 general limitations

- Immunohistochemistry and in situ hybridization are multistep diagnostic processes that require specialized training in the selection of the appropriate reagents; tissue selection, fixation, and processing; preparation of the slide; and interpretation of the staining results.
- Tissue staining is dependent on the handling and processing of the tissue prior to staining. Improper fixation, freezing, thawing, washing, drying, heating, sectioning or contamination with other tissues or fluids may produce artifacts, antibody trapping, or false negative results. Inconsistent results may be due to variations in fixation and embedding methods, or to inherent irregularities within the tissue[17].
- Excessive or incomplete counterstaining may compromise proper interpretation of results.
- The clinical interpretation of any staining or its absence should be complemented by morphological studies using proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist.
- Tissues from persons infected with hepatitis B virus and containing hepatitis B surface antigen (HbsAg) may exhibit nonspecific staining with horseradish peroxidase[18].
- Unexpected negative reactions in poorly differentiated neoplasms may be due to loss or marked decrease of expression of antigen or loss or mutation(s) in the gene(s) coding for the antigen. Unexpected positive staining in tumors may be from expression of an antigen not usually expressed in morphologically similar normal cells, or from persistence or acquisition of an antigen in a neoplasm that develops morphologic and immunohistochemical features associated with another cell lineage (divergent differentiation). Histopathologic classification of tumors is not an exact science and some literature reports of unexpected staining may be controversial.
- Reagents may demonstrate unexpected reactions in previously untested tissues. The possibility of unexpected reactions even in tested tissue groups cannot be completely eliminated due to biological variability of antigen expression/target nucleic acid in neoplasms, or other pathological tissues. Contact your local distributor or the regional office of Vision BioSystems to report any unexpected reaction.

IHC • Normal or nonimmune sera from the same animal source as secondary antisera used in blocking steps may cause false negative or false positive results due to autoantibodies or natural antibodies.

IHC • False positive results in IHC may be seen due to nonimmunological binding of proteins or substrate reaction products. They may also be caused by pseudoperoxidase activity (erythrocytes), endogenous peroxidase activity (cytochrome C), or endogenous biotin (for example, liver, breast, brain, kidney) depending on the type of immunostain used[15].

IHC • False negative cases in IHC may result from various factors, including true antigen decrease, loss or structural change during tumor "dedifferentiation", or artefactual change during fixation or processing. As with any immunohistochemical test, a negative result means that the antigen was not detected, not that the antigen was absent in the tissues assayed.

ISH • False positive results in ISH may be seen due to cross-reactivity of the probe to other nucleic acid sequences as well as nonspecific binding of probe or detection reagents to tissue or tissue components[17]. Negative tissue and reagent controls should be included in testing to help identify false positive staining.

ISH • DNA and RNA are subject to degradation by nuclease activity[8,18]. Therefore, it is important to test the Positive Control Probe with patient tissue in parallel with specific probe and patient tissue to detect nucleic acid degradation. The choice of fixative influences conservation of nucleic acids, tissue fixed in 10% neutral buffered formalin is recommended for this reason[18]. As with any in situ hybridization test, a negative result means that the nucleic acid was not detected, not that the nucleic acid was absent in the tissues assayed.

13.6 key to symbols on labels

In Vitro Diagnostic Medical Device

Batch code

Catalog Number

Serial number (Unique Pack Identifier)

Do not reuse

CE marking of conformity

Consult instructions for use

Caution, consult accompanying documents

Fragile, handle with care

Manufacturer

Authorized Representative in the European Community

Use by (expiry date)

Temperature limitation

13.7 references

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14 specifications

14.1 system

Maximum number of Bond™ Processing Modules	5 (multiple Processing Modules require an Ethernet hub).
Network connection requirements	Ethernet IEEE802.3, 10 BASE T
Network cable	Direct connection: RJ45 Shielded, Crossover
Network cable	Connecting through hub: RJ45 Shielded
Network cable connectors	RJ45
Ethernet hub (for up to 5 Processing Modules)	Ethernet IEEE802.3 10 BASE T (1 port for each PM plus 1 port for the host computer)
Host computer specifications	The host computer must be supplied by Vision BioSystems
Host computer regulatory requirements	UL Listed (UL 60950 or UL 1950), IEC 60950 certified.

14.2 processing module

14.2.1 physical

Dimensions	W — 760 mm (29.9 in) H — 703 mm (27.6 in) D — 775 mm (30.5 in)
Weight (dry)	120 kg (265 lb.)
Clearance requirements	600 mm (24 in) above 0 mm left 150 mm (6 in) right 0 mm at back, however users must be able to disconnect the mains power cable without moving the Processing Module.
Maximum distance to external bulk waste container	1 meter (40 in)

14.2.2 electrical

Operating voltage	100 to 240 V~
Mains frequency	50/60 Hz
Power consumption	1000 VA (Bond-max) 600 VA (Bond-x)

14.2.3 environmental

Maximum operating temperature	35 °C (95 °F)
Minimum operating temperature	5 °C (41 °F)
Temperature required to meet staining performance requirements	18–26 °C (64–79 °F)
Operating humidity (noncondensing)	10 to 80% RH
Maximum operating altitude	0 to 1600 m (5250 ft.) above sea level
Sound pressure level output (at 1 m)	< 65 dB
Maximum heating energy output	1000 VA
IEC 61010-1 classifications	Protective class 1 Pollution degree 2

14.2.4 operating

Slide capacity	30 at a time. Finished batches may be replaced continuously.
Reagent container capacity	7 mL and 30 mL
Reagent container dead volume	555 µL (7 mL) and 1618 µL (30 mL)
Titration container capacity	6 mL
Titration container dead volume	200 µL
Number of reagent containers	36
Bulk reagent container capacity	1 L or 2 L
Hazardous waste container capacity	2 L
Standard waste container capacity	4 L (Bond-x only)
External bulk waste container capacity	9 L (standard for Bond-max, optional for Bond-x)
Chemical compatibility	All Bond reagents 70% alcohol solution
Temperature indication	Defaults (these can be changed by service representatives): Warm: 37 °C, Hot: 80 °C

14.2.5 microscope slides

Dimensions	Width — 24.64–26.0 mm (0.97–1.02 in) Length — 74.9 – 76.0 mm (2.95–2.99 in) Thickness — 0.8 – 1.3 mm (0.03–0.05 in)
Label area	Width — 24.64–26.0 mm (0.97–1.02 in) Length —16.9 – 21.0 mm (0.67–0.83 in)
Material	Glass, ISO 8037/1
Usable area	Refer to the following diagrams. The dispense volume refers to the settings you can choose when setting up slides using the Bond software (see "working with cases" on page 121)

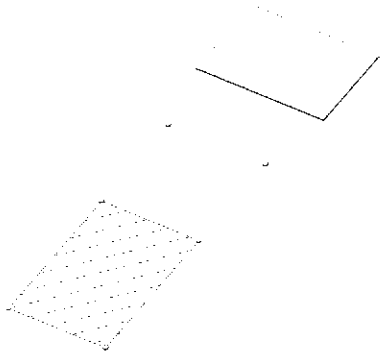

Figure 184: Bond-x 100 µL

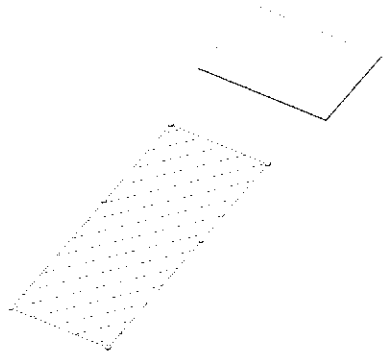

Figure 185: Bond-x 150 µL

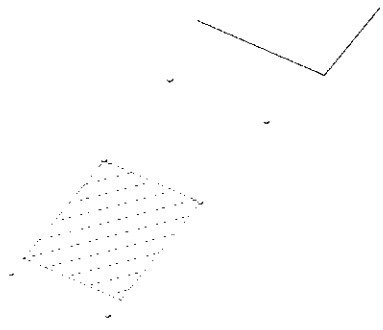

Figure 186: Bond-max 100 µL

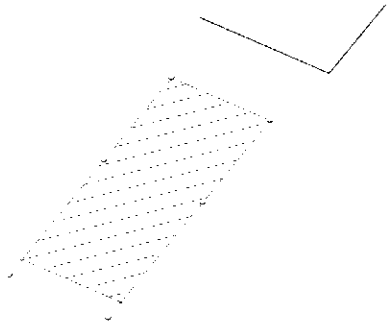

Figure 187: Bond-max 150 µL

14.2.6 transport and storage

Storage temperature	-46 to +71 °C (-51 to +160 °F)
Storage humidity (noncondensing)	10 to 80% RH
Shipping methods	Road and airfreight compatible.

14.2.7 regulatory approvals

EMC (Europe)	EN61326:1997 (including Amendment 1:1998)
EMC (USA)	FCC Part 15 Class B
Safety (UL USA)	UL 61010A-1, First Edition
Safety (UL Canada)	CAN/CSA C22.2 No. 1010-1
Safety (Europe)	IEC 61010-1 IEC 61010-2-010
UL Listed	File Nº E177955-V1-S4

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